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6/LC/P12756.GB

03FEB03 E781913-1 D02059
P01/7700 0.00-0302393.4
03 FEB 2003

2. Patent application number
(The Patent Office will fill in this part)

0302393.4

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

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Patents ADP number *(if you know it)*

7774219001

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

MEDICAL NEEDLE ASSEMBLIES

5. Name of your agent *(if you have one)*

Sanderson & Co.

"Address for service" in the United Kingdom to which all correspondence should be sent *(including postcode)*

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Patents ADP number *(if you know it)*

1446001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*
GB	02 14452.5	22/06/2002

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

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11. I/We request the grant of a patent on the basis of this application.

Sanderson & Co.
Agents for the applicant

Signature

Date
31st January 2003

12. Name and daytime telephone number of person to contact in the United Kingdom

F.C. Gillam – 01206 571187

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MEDICAL NEEDLE ASSEMBLIES

This invention relates to a safety arrangement for a medical needle having a mount end and a sharp tip, intended for penetration of a human or animal body, or for other medical uses such as the penetration of a pierceable membrane of an intravenous medication system. The invention further relates to a safety arrangement including a medical needle as aforesaid, ready for use. For convenience, in the following all such medical uses will be described simply as the penetration of a body, even though specific embodiments may be intended for other medical uses.

In my co-pending British Patent Application No. 0214452.5, filed on 22nd June 2002 ("my earlier application"), I have described and claimed various medical needle assemblies furnished with a sleeve which is slidable along the length of a supported needle and which automatically locks in a needle protecting position following withdrawal of the needle from a penetrated body. This locking of the sleeve in a protecting position occurs without an operator having to perform any extra step on withdrawing the needle from a body; the assembly is thus a passive protection device which may be contrasted with an active protection device, where an operator is required to perform an extra step in order to protect a needle, following the withdrawal of the needle from a body. The requirement to perform an extra step leaves the needle unprotected for a longer period than with a passive protection device and further the performance of that extra step exposes the operator to a potentially hazardous situation, where needle-stick accidents can occur.

The full disclosure of my earlier application is incorporated herein by this reference thereto. In my earlier application aforesaid, I have claimed a medical needle assembly comprising:

– a needle having a mount end and a sharp tip;

– a support wall carrying the mount end of a needle so as to project away therefrom;

– a sleeve mounted on the support wall and being slidable with respect thereto from an initial position where the sleeve covers at least the greater part of the projecting needle to a retracted position where the tip of the needle is exposed along with a part of the needle extending back from the tip, and then to a protecting position where the sleeve covers the needle tip and at least part of the needle projecting back from its tip;

– a spring arranged to urge the sleeve away from the support wall;

– a locking member projecting forwardly from the support wall, the locking member being movable between a free position where the locking member extends generally parallel to the needle axis and the sleeve may slide to its withdrawn position and a blocking position where the locking member is disposed between the support wall and the sleeve and is off-axis with respect to the needle axis, thereby blocking movement of the sleeve away from its initial position; and

– control means which holds the locking member in its free position until tripped by movement of the sleeve away from its initial position, the control means thereafter permitting the locking member to move to its blocking position on movement of the sleeve to its protecting position, so preventing subsequent movement of the sleeve away from its protecting position.

Further, I have also claimed an assembly for supporting a medical needle which has a mount end and a tip, the assembly comprising:

– a tubular housing having a rear wall provided with an internal mount portion adapted to support the mount end of a needle, the housing being open

at its opposed end so that a supported needle may extend from the mount portion and project out of the opposed end;

– a sleeve slidably mounted within the housing to surround a supported needle, the sleeve being slideable with respect to the housing from an initial position where the sleeve will cover at least the greater part of a supported needle projecting from the housing to a retracted position exposing the tip and part of a supported needle extending back from the tip, and then to a protecting position where the sleeve covers that part of the needle projecting beyond the housing including the needle tip, the sleeve having a rear end nearer the rear wall of the housing and there being means to prevent the sleeve sliding off the housing;

– a locking member provided within the housing, the locking member having a base disposed between the rear end of the sleeve and the rear wall of the housing and a locking section which extends from the base generally parallel to the length of the sleeve and co-operable with the sleeve;

– a control member also receivable within the sleeve and which initially supports the locking section of the locking member to lie substantially parallel to the sleeve axis, there being a releasable connection between the sleeve and the control member; and

– a spring disposed to urge apart the sleeve and the locking member;

in which assembly:

– with the sleeve in its initial position the control member is disposed adjacent the rear end of the sleeve, engaged with the locking section of the locking member;

– on movement of the sleeve to its retracted position the control member releasable connection is released so permitting the control member to move into the sleeve, the control member guiding the locking section into the sleeve; and

– on the sleeve subsequently moving to its protecting position under the action of the spring, the base of the locking member is urged to bear on the housing rear wall and the locking section of the locking member

engages behind the rear end of the sleeve, so preventing subsequent retraction of the sleeve from its protecting position.

Consequent upon further research and development, the assemblies of my previous application have been improved and adapted to suit particular circumstances. The present invention results from that work and provides modified forms of needle protection devices, having enhanced characteristics. Accordingly, this invention provides a safety arrangement for a medical needle having a mount end and a sharp tip, which arrangement comprises:

– a support adapted directly or indirectly to carry the mount end of a needle so that the needle projects forwardly away therefrom;

– a sleeve mounted directly or indirectly on the support and being slideable with respect thereto from an initial position where the sleeve covers at least the greater part of a carried needle to a retracted position where the tip of a carried needle and a part of the needle back from its tip is exposed, and then to a protecting position where the sleeve covers the needle tip and at least part of the needle back from its tip;

– resilient means arranged to urge the sleeve towards its protecting position;

– a blocking member at least a part of which projects forwardly from the support, the blocking member being movable between a non-blocking position where the blocking member extends generally parallel to the needle axis and the sleeve may slide to its retracted position and a blocking position where the blocking member has moved from its non-blocking position so as to be disposed between the support and a part of the sleeve, thereby blocking movement of the sleeve away from its protecting position; and

– control means which releases the blocking member for movement from its non-blocking position to its blocking position on movement of the sleeve away from its initial position towards its retracted position, so that on subsequent movement of the sleeve to its protecting position the blocking

member will thereafter block movement of the sleeve away from its protecting position.

It will be appreciated that the safety arrangement of this invention may be provided with an integral medical needle, or may be adapted to receive a medical needle shortly before being used to undertake penetration of a body. Either way, on withdrawing the needle from a body, the safety arrangement operates fully automatically and without the need for any operator intervention (i.e. passively), to furnish a sleeve over the exposed part of a needle and to block that sleeve in a fully protecting position, from which the sleeve cannot be withdrawn short of destroying the safety arrangement. Thus, an operator is automatically and effectively protected against needle-stick injuries, following the completion of a medical procedure using the needle, when equipped with the safety arrangement.

Various preferred aspects of the safety arrangement of this invention are defined in the appended claims. Several embodiments of the safety arrangement will now be described, reference being made to the accompanying drawings in which:

Figures 7A to 7J show a sixth embodiment of safety arrangement, intended for use with a pre-filled syringe or a syringe to be filled from a vial of medicament;

Figures 8A to 8J show a seventh embodiment generally similar to that of Figures 7A to 7J;

Figures 9A to 9E show an eighth embodiment intended for use with an injection device intended to take a cartridge of medicament, suitable for self-injection;

Figures 10A to 10C show an embodiment of packaging suitable for use with the safety arrangement of Figure 9;

Figures 11A to 11M show a ninth embodiment of safety arrangement, intended for use with a single-use throw-away syringe;

Figures 12A and 12B show a tenth embodiment of safety arrangement similar to that but more compact than the eighth embodiment of Figure 9; and

Figures 13A to 13C show an eleventh embodiment of safety arrangement again for use with an injection device intended to take a cartridge of medicament.

[*Note: The suffix I is not used in the identification of the Figures to avoid confusion with the numeral 1*]

The embodiments of safety arrangement for a medical needle shown in the accompanying drawings are developments of the embodiment of Figure 6 of my earlier application and so use the same basic operating principle. The embodiments of Figures 1 to 5 of my earlier application all employ a separate and movable control member such as member 27 of Figure 1, whereas the embodiment of Figure 6 and also the present embodiments have no such control member.

Figures 7A to 7J

The sixth embodiment is shown in Figures 7A to 7J. The safety arrangement is intended for use with a syringe having a body 80 fitted with a needle 81 in the course of manufacture. The syringe has a plunger 82 with a piston 83 within the bore of the syringe, so that liquid may be drawn into the syringe through the needle 81 by withdrawing the plunger 82 from its fully

inserted position, the medicament subsequently being expelled through the needle 81 by depressing that plunger.

The plunger 82 has an X-shaped cross-section and differs from the plunger of a conventional syringe in that the outer edge of each arm of the X-shaped cross-section is provided with a protuberance 84, disposed approximately one quarter of the way along the length of the plunger, from the piston end. In the region of each protuberance, the respective arm has a through-slot 85 to enable radially inward movement of the protuberances. The protuberances 84 define a stop position for the plunger on being moved into the bore by the application of axial pressure to the remote end 86 of the plunger. When the protuberances reach the rear end of the syringe body, an increased force is momentarily required to move the plunger deeper into the syringe body.

The safety arrangement for use with the syringe described above comprises a tubular support 87 having a bore in which the syringe body 80 is snugly received. The needle is thus indirectly carried by the support, through the syringe itself. Formed within that bore is an internal rib 88 which limits the movement of the syringe body into the bore. The part of the support 87 which overlies the syringe body has a greater wall thickness and slidably carries a sleeve 89. The forward end 89A of the sleeve has an internal radial flange 90 formed with a central hole 91 through which the needle 81 may project, the flange being provided with an upstand 92 which projects internally of the sleeve towards the syringe, the upstand having a relatively small arcuate extent, typically of only a few degrees. Partway along the length of the sleeve 89, an annular shoulder 83 is formed by a change in the internal and external

diameters of the sleeve and between that shoulder 93 and the flange 90, there is formed an inwardly-projecting annular rib 94 (Figure 7J). A further internal rib 95 (Figure 7H) is formed at the rearward end of the sleeve, over which an out-turned flange 96 at the rear end of the syringe body must ride to permit the sleeve to slide rearwardly from that position shown in Figures 7A, 7B and 7J.

A tubular blocking member 97 is slidably carried on the forward end portion of the support 87 and is urged forwardly by a helical compression spring 98, acting between the internal rib 88 of the support and an internal flange 99 formed at the forward end of the blocking member 97. Externally, the blocking member 97 has at its forward end an outwardly-projecting flexible lip 100 slidable within the smaller diameter portion of the sleeve 89 but movable over the internal rib 94 of the sleeve only when an increased force is applied to the sleeve, relative to the blocking member. This is shown on an enlarged scale in Figure 7K.

The starting position is shown in Figures 7A, 7B, 7J and 7K, with the safety arrangement set ready for use, though the plunger will be fully forward, to permit filling of the syringe. Alternatively, the syringe could be pre-filled, in which case the plunger will be set as shown, and the filling step will be omitted.

If the syringe is to be filled, the nose part of a phial (not shown) of medicament is inserted into the hole 91 at the forward end of the sleeve 89 and is pushed gently on to the needle 81, moving the sleeve rearwardly with respect to the syringe by riding the further rib 95 of the sleeve over the out-turned flange 96 of the syringe body 80. During this, the blocking member 97 moves rearwardly, simultaneously with the sleeve, against the action of spring 96. The

combined force of the spring 96 acting on the blocking member 95 and the force required to ride the further rib 95 over the out-turned flange 96 should be less than that required to move the lip 100 of the blocking member 97 over the rib 94 of the sleeve. As such, during the phial-filling operation, the blocking member 97 remains with its lip 100 rearward of rib 94 of the sleeve (Figure 7C).

Following charging of the syringe and then the removal of the phial, the mechanism is ready for performing an injection. The operator applies a gentle force on the remote end 86 of the plunger by applying a reaction to the sleeve 89 and this has the effect of moving the plunger forwardly until the protuberances 84 are about to enter the syringe body, and also of pulling the sleeve rearwardly, to cause the needle 81 to project from the forward end of the sleeve. However, this can be achieved only by having the lip 100 of the blocking member 97 ride over the rib 94 of the sleeve 89 and so moving forwardly towards the flange 90 of the sleeve, as shown in Figure 7D. Rearward movement of the sleeve may continue until the shoulder 93 engages that part of the support having a thickened wall thickness as shown in Figure 7E. The needle 81 is then projecting beyond the flange 90 to its greatest possible extent.

The assembly is used in this condition to perform an injection, firstly by pushing the needle 81 into a body at the injection site and then pushing the plunger fully forwardly, the protuberances 84 moving inwardly to permit this, as shown in Figure 7F. The condition of Figure 7E could instead be achieved by using the syringe with the connected assembly to perform a stabbing motion

against a body, so that the engagement of the flange 90 at the forward end of the sleeve moves the sleeve rearwardly with respect to the syringe.

On removing the syringe assembly from a body, by pulling rearwardly on the plunger and releasing the sleeve, or by pulling on the sleeve and releasing the plunger, the spring 98 will cause relative separation of the forward end of the sleeve and the support 87, the spring acting on the flange 99 of the blocking member 97 to maintain contact between the forward end of the blocking member and upstand 92. Eventually, the separation will be so great that the blocking member comes free of the support 87 and the spring force acting on the blocking member will allow it to cant over so that its axis lies at an acute angle to the axis of the sleeve and support member – Figure 7G. When in this position, the blocking member 97 lies between the flange 90 of the sleeve and the forward end of the support 87 and so physically blocks subsequent rearward movement of the sleeve 89, with respect to the support and syringe.

When in the setting of Figure 7G, the needle is securely protected against exposure. Having regard to the tubular nature of the blocking member 97, a very high force must be applied to the sleeve 89 in order to expose the needle, in effect either destroying the sleeve or the blocking member.

Figures 8A to 8H

The seventh embodiment is shown in Figures 8A to 8H. This seventh embodiment is generally similar to the sixth embodiment of Figures 7A to 7J and like parts are given like reference numbers and will not be described again in detail.

The seventh embodiment differs from the sixth embodiment in that the part of the support 104 surrounding the syringe 80 does not have a significantly increased wall thickness, though a step 105 is formed between forward and rearward parts of that support, in order to serve as a backstop for movement of the blocking member 97. At its rearward end, the support 104 has an increased internal diameter portion 106, to permit the accommodation therein of the out-turned flange 96 of a syringe, which may have an entirely conventional plunger not including the protuberances 84 of the sixth embodiment. That increased diameter part 106 supports a tube 107 projecting forwardly coaxial with the support itself but with an annular space between the tube and the support. A sleeve 108 is slidably mounted within the tube 107, forward movement of the sleeve being limited by an external rib 109 around the rear end of the sleeve and an internal shoulder 110 formed within the tube 107.

The sleeve has two axially-spaced internal ribs 111 and 112, each of which can interact with the lip 100 of the blocking member 98 in a generally similar manner to that described with respect to the sixth embodiment.

Figures 8A and 8B show the initial position, with a slight clearance between the rearward end of the blocking member 97 and the step 105 of the support 104. On loading a phial for the filling of the syringe, initially the sleeve moves rearwardly until the rear end face of the blocking member engages the step 105 (Figure 8C) and continued rearward pressure on the sleeve then allows the lip 100 of the blocking member to ride over the first rib 111, then to move forwardly to engage the second rib 112 (Figure 8D). In this setting, the syringe may be filled from a phial and on releasing the phial from the syringe,

the sleeve and blocking member will together move forwardly to the position shown in Figure 8E, so covering the needle once more.

From this setting, operation is essentially as described in relation to the sixth embodiment. Thus, the syringe assembly is used to make an injection in the course of which the blocking member 97 moves fully forwardly (Figure 8F) and then further rearward movement of the sleeve allows the needle to project to its greatest possible extent (Figure 8G), as the plunger is depressed (Figure 8H). On withdrawing the needle, the sleeve 108 is moved forwardly under the action of the spring bearing on the blocking member; finally the blocking member 97 comes free of the support 104 and is canted over (Figure 8J) so as to provide a physical block between the support and the flange of the sleeve, as described above.

Figures 9A to 9E

The eighth embodiment is shown in Figures 9A to 9E and is a modified form of the sixth embodiment (Figures 7A to 7J) intended for use with an injection device adapted to receive a cartridge of medicament. For example, the safety assembly of this eighth embodiment may be employed with a medicament-dispensing "pen" intended for dispensing a pre-selected but variable dose of insulin, for self-injection.

A support 115 directly carries a needle 116 the rear end of which projects into the space within the support 115, so that on fitting the support to an injection device carrying a cartridge of medicament, the rear end of the needle will penetrate a membrane at the forward end of the cartridge. The

needle 116 so thus communicates with the interior of the cartridge, for dispensing of the medicament.

A sleeve 117 is slidably mounted on the rearward part 118 of the support 115 and has an in-turned lip 119 to prevent the sleeve moving forwardly with respect to the support, from the position shown in Figures 9A and 9B. The forward end of the sleeve, its rib 94 and the blocking member 97 are all as described with respect to the sixth embodiment and are given like reference characters; these components will not be described further here.

In the initial position shown in Figures 9A and 9B, the spring 98 is shown fully compressed but the force exerted thereby on the blocking member 97 is insufficient to move the lip 100 of the blocking member over the rib 94 of the sleeve. Equally, as discussed above, the support 115 cannot move out of the sleeve by virtue of the in-turned lip 119 at the rear end of the sleeve.

When an injection (and typically a self-injection of insulin) is to be made, the safety arrangement is mounted on the front end of an injection pen, the appropriate dose is set and then the pen is used to perform a stabbing motion on the selected body site. The flange 90 at the forward end of the sleeve 117 serves to ensure that the needle 116 enters the body essentially perpendicularly and the impact force on the body of the flange 90 at the forward end of the sleeve 117 serves to cause rib 94 to ride over lip 100 of the blocking member. This allows the blocking member 97 to move forwardly under the action of spring 98, as shown in Figure 9C. From there, the operation is essentially as described above with reference to the sixth embodiment of Figure 7. The injection is performed with the assembly set as shown in Figure 9D and,

following withdrawal of the needle, the sleeve is blocked in its protecting position as shown in Figure 9E.

Figures 10A to 10C

Packaging for the eighth embodiment of Figure 9, is illustrated in Figures 10A to 10C. The safety device itself shown in these Figures is identical to that of Figures 9A to 9E and will not be described again. Further, the same reference numbers are used to designate the same components.

The packaging comprises a moulded plastics cylindrical tube 120 closed at one end by wall 121, and shaped to receive the safety assembly 122 of Figures 9A and 9B in its initial condition as shown in Figures 10A and 10B. When so received, the tube 120 containing the assembly 122 may be rendered sterile, using known techniques, and then sealed by a cover foil 123 heat-sealed to a flange 124 around the open end of the tube 120. That foil has a flap 125 to enable easy opening of the tube, when the assembly 122 is to be used.

As shown in the drawings, a cylindrical projection 126 upstands axially from the end wall 121 of the tube 120. That projection has such a length that when the assembly 122 is fully received in the tube 120, the inner end of the projection engages the blocking member 97 of the assembly and so prevents that blocking member moving forwardly under the action of spring 98, notwithstanding the interengagement of the lip 100 with rib 94 of the sleeve 117.

After opening the tube, the injection pen is pressed on to the assembly 122 while still in the tube 120 and then the tube is pulled free of the assembly.

Following use of the safety assembly to make an injection, the sleeve protects the needle as the blocking member prevents the sleeve being withdrawn to expose the needle, as shown in Figure 11C. The assembly may then be inserted into the tube 120 but the other way round (that is, with the needle pointing towards the open end of the tube) and, having regard to the draw of the tube, as the assembly is pushed fully home it forms a tight frictional fit within the tube. As such, it will be extremely difficult to withdraw the assembly once more and the needle is fully protected, for disposal.

Figures 11A to 11M

The ninth embodiment is shown in Figures 11A to 11M. This safety arrangement is intended for use with a single-use luer-slip or luer-lock syringe having a syringe body 148 moulded from a plastics material and provided with a luer-lock taper spigot 149 at its forward end, for receiving a correspondingly profiled needle hub. Such syringes are well known in the art and are very widely used; following use of the syringe, it is thrown away with the needle still connected to the syringe.

The safety arrangement of this ninth embodiment has a support 128 provided with a needle 129, the support defining a socket to receive the luer-lock spigot 149 at the forward end of the syringe 148. The support 128 defines an outer cylindrical surface 130 on which a blocking member 131 is slidably carried, a spring 132 acting between the support 128 and the forward end of the blocking member 131. A two-part sleeve 134 surrounds the support 128 and the blocking member 131, the rearward end portion 135 of the sleeve defining a cylindrical bore 136 within which the outer surface of the syringe

body 148 is slidably receivable. The transition between that rearward end portion 135 and the central region 137 of the sleeve forms a shoulder 138 against which both the support 128 and the blocking member 131 abut, with the assembly in its initial position as shown in Figures 11A and 11B.

The forward end portion 139 of the sleeve 134 has an enlarged diameter and carries a front sleeve part 140 configured similarly to the front part of the sleeve of the sixth and eighth embodiments. Thus, this front part 140 has a flange 90 at its forward end together with an upstand 92 on that flange, and an annular rib 94 is formed internally, spaced rearwardly from the flange 90. Further, the forward end of the blocking member 131 has a lip 100 to co-act with the rib 94, again as described above.

A protective tubular cap 142 is moulded integrally with the front part 140 but is connected to the front part by relatively weak ribs around the hole 91 in the flange 90. The cap projects internally into the sleeve by a small distance, as shown. The central hole in the flange 99 of the blocking member is sufficiently large to permit the internally projecting part of the cap 142 to pass therethrough, and the blocking member has an internal abutment 143 spaced rearwardly from the front face of that member.

The initial position of the safety assembly, as supplied for use, is as shown in Figures 11A and 11B. It is connected to a syringe body 148 by inserting the forward end of the syringe into the bore 136 of the sleeve 134 and engaging the spigot 149 with the support 128. As the syringe body moves deeper into the sleeve 134, the support 128 is also moved forwardly as shown in Figure 11C, commencing the engagement of the luer-lock.

This continues until the support 128 abuts the rearward end of the cap 142, within the sleeve 134 (Figures 11D) and continued pressure on the syringe then fully connects the luer-lock, between the syringe spigot 149 and the support 128 (Figure 11E). Depending upon the strength of the connection between the cap 142 and the front part 140 of the sleeve, it might be necessary to apply endwise pressure on the cap 142 – for example by supporting the forward end of the cap 142 on a hard surface such as a table, and pressing the syringe body downwardly to engage the luer-lock.

Following full engagement of the spigot 149 with the support 128, release of the safety device returns it to its original setting, as shown in Figure 11F. Then, the cap 142 may be broken away by applying a sideways force thereto (Figure 11G). During this operation, the needle is withdrawn from the cap and so there is no risk of damage to the sharp end of the needle as the cap is broken away; this can be contrasted with the usual arrangement employed with single-use syringes where great care must be taken to move the cap axially, to avoid catching, and so burring, the sharp end of the needle.

The syringe is filled with an appropriate quantity of medicament by gently pressing a phial 145 on to the flange 90 at the forward end of the sleeve 134, so permitting the syringe and connected needle to move deeper into the safety assembly. The needle penetrates the pierceable membrane 146 of the phial, to permit the extraction of medicament therefrom by withdrawing the syringe plunger. Only light pressure is required to achieve this penetration, and so the lip 100 of the blocking member 131 remains rearwardly of the rib 94 within the front part 140 of the sleeve (Figure 11H).

Following filling of the syringe, the phial 145 is pulled away from the needle, so allowing return of the safety assembly to its initial setting, though without the cap 142 and so ready for use to perform an injection (Figure 11J).

From here, the operation of the safety assembly is much as has been described above with reference to the previous embodiments. On performing a stabbing action to effect needle penetration into a body, the sleeve 134 initially moves rearwardly with respect to the support 128, taking the blocking member 131 with it until the support engages the annular abutment 143 within the blocking member 131 (Figure 11K). Continued rearward movement of the sleeve causes the lip 100 to ride over the rib 94 until maximum projection of the needle is achieved (Figure 11L), where the front of the blocking member 131 engages the upstand 92 on the flange 90 of the sleeve 134. Finally, after completing the injection and then withdrawing the needle from a body, the sleeve moves forwardly with respect to the syringe body, under the action of the spring 132 bearing on the blocking member. The flange 99 of the blocking member remains in engagement with the flange 90 of the sleeve 134 so that when the sleeve has moved fully forwardly with respect to the syringe and connected support 128, the blocking member is free to cant over and fulfil its blocking function (Figure 11M).

Figures 12A and 12B

Figures 12A and 12B show a modified form of the eighth embodiment, of Figure 9. This modified form has a shorter overall length, achieved by providing a two-part support 155 the outer part 156 of which is folded back on itself in order to provide a surrounding annular space 157 within which the blocking

member is slidably received. The rib 94 of the sleeve 117 is correspondingly nearer its flange 90. Thus, in the initial setting, the blocking member is disposed forward of the front end of the support 155 and so the spring is not fully compressed. Further, the distance the blocking member may move before engaging the upstand 92 is much reduced.

In other respects, the construction and operation of this modified form corresponds to that of the eighth embodiment (Figure 9) and so will not be described in detail again, here.

Figures 13A to 13C

Figures 13A to 13C illustrate a tenth embodiment of this invention which, while generally similar to that of the eighth embodiment (Figure 9) differs in one important detail. However, like parts with those of Figures 9A to 9E are given like reference numbers.

The embodiment of Figures 13A to 13C does not include a rib 94 within the sleeve 89, so that the blocking member is held by spring 98 in a fully forward position, when the assembly is in its initial setting (Figures 13A and 13B). However, the blocking member is maintained coaxial with the support 115 and sleeve 117 by means of a slip ring 159, slidably carried but a light frictional fit on the support 115. The rearward end of the blocking member 97 is received within a counter-bore in the slip ring 159.

On performing an injection, the sleeve 117 is moved rearwardly, taking the slip ring 159 with it. Then, following completion of the injection, the sleeve and blocking member move forwardly once more but the slip ring 159 remains in its rearmost position, on the support 115. Thus, on the sleeve and blocking

member moving fully forwardly, the blocking member moves to its blocking position as shown in Figure 13C, thus rendering the assembly safe with the sleeve blocked against movement away from its protecting position.

•••◆•◆•◆•••

In all of the above embodiments, the respective sleeves may be made transparent, translucent or provided with a transparent or translucent window. By manufacturing the respective blocking member from a strongly-coloured material, the position of the blocking member within the sleeve will readily be discernible. Then, when the safety device has been used and the blocking member is fully forward, this will immediately be apparent on looking at the assembly.

CLAIMS

1. A safety arrangement for a medical needle having a mount end and a sharp tip, which arrangement comprises:

– a support adapted directly or indirectly to carry the mount end of a needle so that the needle projects forwardly away therefrom;

– a sleeve mounted directly or indirectly on the support and being slideable with respect thereto from an initial position where the sleeve covers at least the greater part of a carried needle to a retracted position where the tip of a carried needle and a part of the needle back from its tip is exposed, and then to a protecting position where the sleeve covers the needle tip and at least part of the needle back from its tip;

– resilient means arranged to urge the sleeve towards its protecting position;

– a blocking member at least a part of which projects forwardly from the support, the blocking member being movable between a non-blocking position where the blocking member extends generally parallel to the needle axis and the sleeve may slide to its retracted position and a blocking position where the blocking member has moved from its non-blocking position so as to be disposed between the support and a part of the sleeve, thereby blocking movement of the sleeve away from its protecting position; and

– control means which releases the blocking member for movement from its non-blocking position to its blocking position on movement of the sleeve away from its initial position towards its retracted position, so that on subsequent movement of the sleeve to its protecting position the blocking member will thereafter block movement of the sleeve away from its protecting position.

2. A safety arrangement as claimed in claim 1, wherein the blocking member when in its blocking position extends at an acute angle to the needle axis.

3. A safety arrangement as claimed in claim 2, wherein the blocking member is tubular and when in its non-blocking position is generally co-axial with the sleeve and needle.

4. A safety arrangement as claimed in any of the preceding claims, wherein one end of the blocking member when in its blocking position co-operates with a wall portion of one of the support and the sleeve to apply a turning moment to the blocking member about an axis transverse to the length of the sleeve, so moving the second end of the blocking member to block retracting movement of the sleeve.

5. A safety arrangement as claimed in claim 4, wherein one end of the blocking member has an off-set boss projecting towards said adjacent wall portion of said one of the support and the sleeve, whereby on the one end of blocking member being urged towards said adjacent wall portion, the off-set projection applies said turning moment to the blocking member.

6. A safety arrangement as claimed in claim 4, wherein said wall portion has an off-set boss projecting towards the adjacent one end of the blocking member, whereby on said one end of the blocking member being urged towards said wall portion, the off-set projection applies said turning moment to the blocking member.

7. A safety arrangement as claimed in claim 4, wherein one end of the blocking member presents a non-radial face to said adjacent wall portion of said one of the support and the sleeve, whereby on the one end of blocking member being urged towards said adjacent wall portion, the non-radial face applies said turning moment to the blocking member.

8. A safety arrangement as claimed in claim 4, wherein said wall portion presents a non-radial face to the adjacent one end of the blocking member, whereby on said one end of the blocking member being urged towards said wall portion, the non-radial face applies said turning moment to the blocking member.

"*Solid Version*"

9. A safety arrangement as claimed in any of the preceding claims, wherein said support includes a bore in which is receivable a hypodermic syringe having said needle mounted on the forward end thereof such that when the syringe is received within said bore, the needle projects forwardly into the sleeve.

10. A safety arrangement as claimed in claim 9, wherein the sleeve is slidably mounted externally on the support.

"Telescoping Version"

11. A safety arrangement as claimed in claim 9, wherein the sleeve is slidably received within a tubular carrier, which carrier is mounted on said support.

12. A safety arrangement as claimed in claim 10 or claim 11, wherein the forward end of the sleeve has a generally radial inwardly directed flange having a central aperture though which the tip of the needle may project when the sleeve is in its withdrawn position.

13. A safety arrangement as claimed in any of claims 9 to 12, wherein the blocking member is slidably carried on the sleeve but slides off the sleeve under the action of the resilient means to move to its blocking position when released by the control means.

"Throw Away Version"

14. A safety arrangement as claimed in any of claims 1 to 8 for use with a hypodermic syringe having a cylindrical body provided with a spigot at its forward end for receiving a needle having a mounting hub at its rearward end, wherein said support includes a socket for receiving the spigot of a hypodermic syringe, the support being provided with a needle to project forwardly from a mounted syringe with the needle in communication with the spigot, and the sleeve being slideable on the external surface of the syringe body.

15. A safety arrangement as claimed in claim 14, wherein the support has a greater diameter than the external diameter of the syringe body and the blocking member is slideable over said external diameter of the support.

"Cartridge Version"

17. A safety arrangement as claimed in any of claims 1 to 8 for use with an injection device adapted to hold a cartridge of medicament which device has a cylindrical body provided with a spigot at its forward end, wherein said support

includes a socket for receiving the spigot of the device, the support being provided with a needle to project forwardly from the spigot with the rear end of the needle in communication with a cartridge carried by the device, the support having an external wall on which the sleeve is slidably supported.

18. A safety arrangement as claimed in claim 14, wherein the support has a forwardly-directed cylindrical surface of a smaller diameter than the external wall on which the sleeve is slideable, the blocking member being slidably carried on said cylindrical surface.

"Control means" (including TT100 – Fig 6)

19. A safety arrangement as claimed in any of the preceding claims, wherein the control means comprises includes a releasable connection between the sleeve and the blocking member.

20. A safety arrangement as claimed in claim 19, wherein movement of the sleeve towards its retracted position releases the connection to permit the blocking member to move towards its blocking position.

21. A safety arrangement as claimed in claim 20, wherein there is a secondary releasable connection between the sleeve and the blocking member displaced axially from the first-mentioned releasable connection, the secondary releasable connection being released by initial movement of the sleeve towards its withdrawn position, and the first-mentioned releasable connection being released by further movement of the sleeve towards its withdrawn position so freeing the blocking member to move to its blocking position.

22. A safety arrangement as claimed in any one of claims 19 to 21, wherein the releasable connection comprises inter-engaged stops respectively on the mutually sliding surfaces of the blocking member and the sleeve, which stops will over-ride each other on the application of a sufficient axial force thereto.

TT100 – Figs 1 to 5

23. A safety arrangement as claimed in any of claims 1 to 8, wherein there is a control member receivable within the sleeve and which initially supports the blocking member to lie substantially coaxial with the sleeve, there being a

releasable connection between the sleeve and the control member which when released by movement of the sleeve away from its initial position permits the blocking member to move to its blocking position on movement of the sleeve to its protecting position.

24. A safety arrangement as claimed in claim 23, wherein the control member is located partly within the sleeve and partly within the blocking member, when the sleeve is in its initial position.

25. A safety arrangement as claimed in claim 24, wherein the releasable connection is formed directly between the outer surface of the control member and the internal surface of the sleeve.

26. A safety arrangement as claimed in any of claims 23 to 25, wherein the releasable connection comprises inter-engaged stops on both the outer surface of the control member and the internal surface of the sleeve, which stops will over-ride each other on the application of a sufficient axial force thereto.

27. A safety arrangement as claimed in claim 26, wherein the resilient means acts between the control member and an internal flange formed within the blocking member and so indirectly on the sleeve through the releasable connection.

28. A safety arrangement as claimed in claim 27, wherein the sleeve is formed with an internal stop at its forward end, the control member is a free sliding fit within the sleeve, and when the releasable connection is released, the control member moves forwardly under the action of the resilient means into engagement with the internal stop.

29. A safety arrangement as claimed in any of claims 23 to 25, wherein the releasable connection is formed by the control member fitting in the sleeve in a frictionally-engaging manner.

30. A safety arrangement as claimed in claim 29, wherein the resilient means surrounds the blocking member to act directly between one end of the sleeve and the blocking member.

31. A safety arrangement as claimed in claim 29 or claim 30, wherein the control member includes an axial projection which is received in the blocking

member and is withdrawn therefrom by movement of the sleeve towards the needle tip, drawing the control member therewith.

32. A safety arrangement as claimed in claim 31, wherein the length of the axial projection is selected to control the maximum permissible movement of the sleeve towards its retracted position before subsequent movement of the sleeve in the opposite direction locks the sleeve against movement towards a retracted position.

33. A safety arrangement as claimed in any of the preceding claims, wherein the resilient means comprises a helical coil spring.

34. A safety arrangement as claimed in claim 1 and substantially as hereinbefore described, with reference to and as illustrated in the accompanying drawings.

35. A safety arrangement as claimed in any of the preceding claims and in combination with a needle the mount end of which is secured to the support, to project forwardly therefrom.

16 sheets

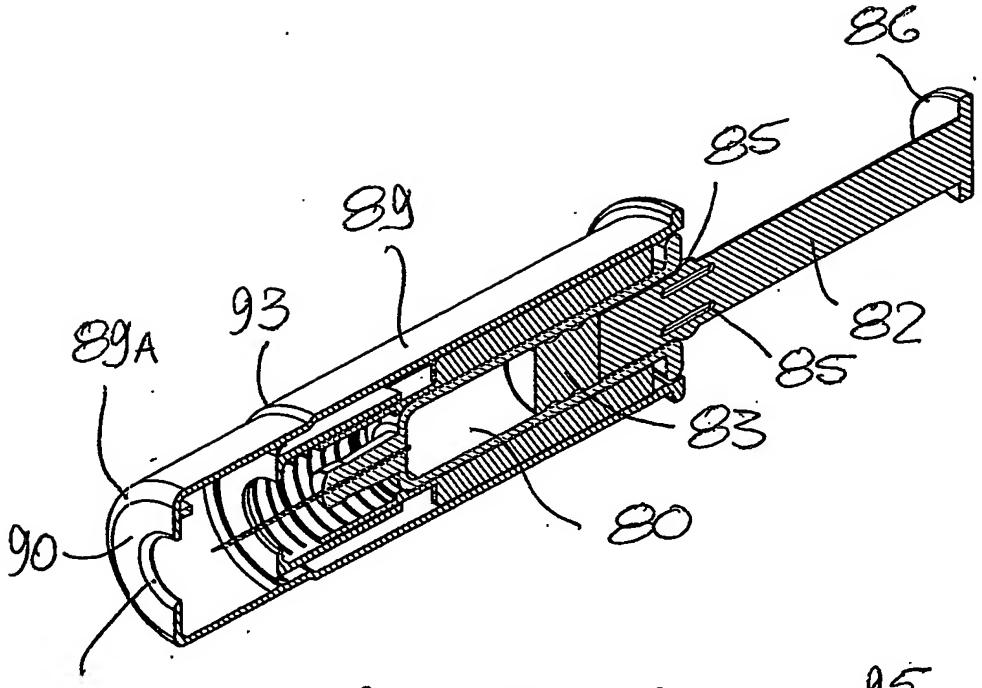


FIG 7A

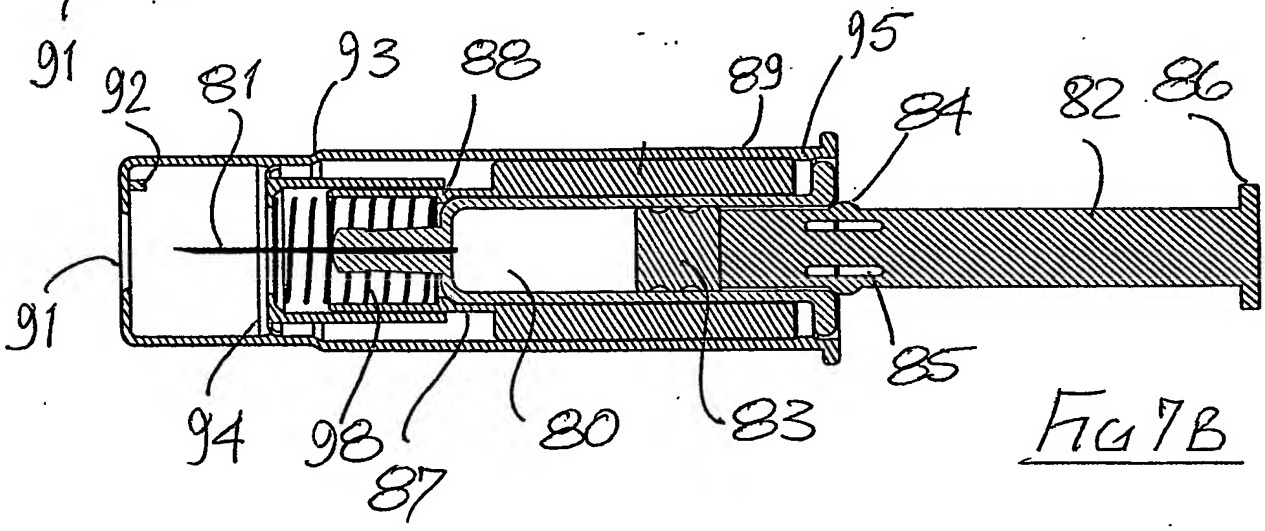


FIG 7B

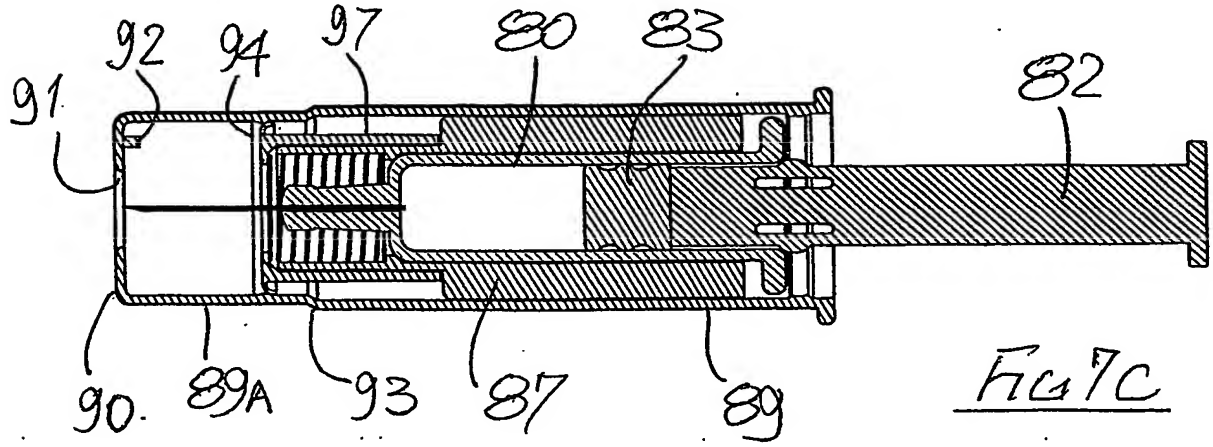


FIG 7C

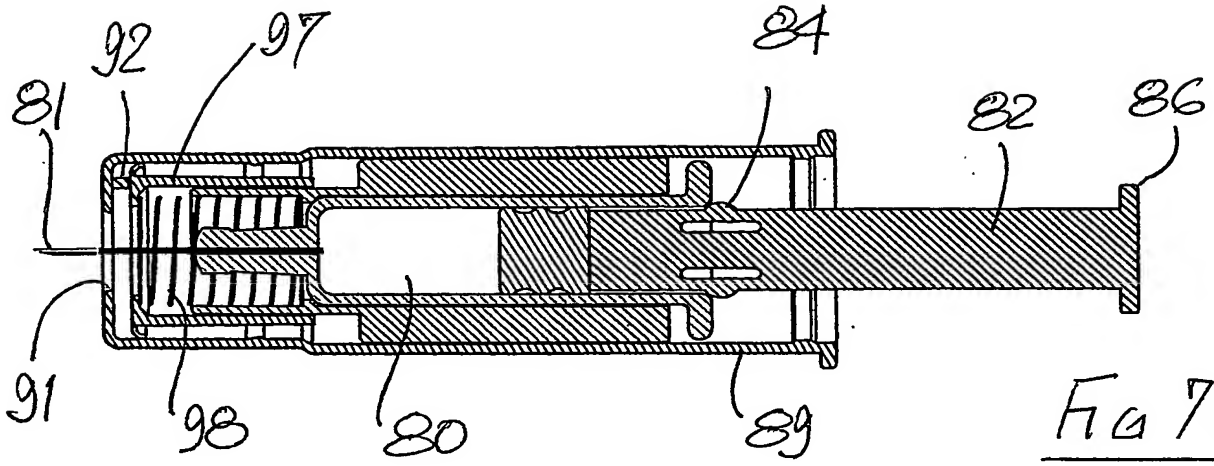


FIG 7D

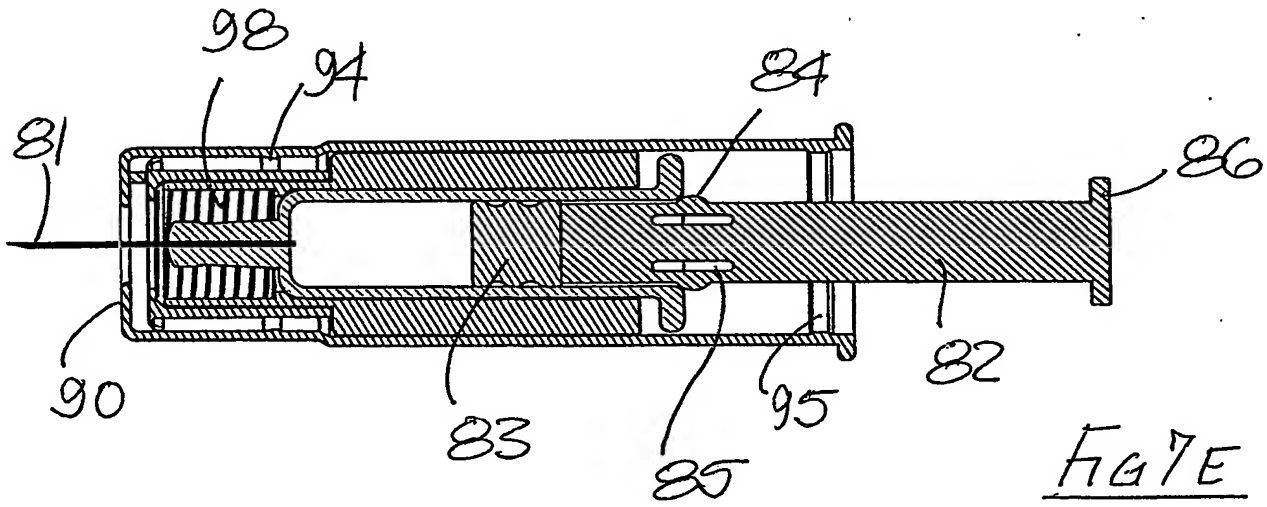


FIG 7E

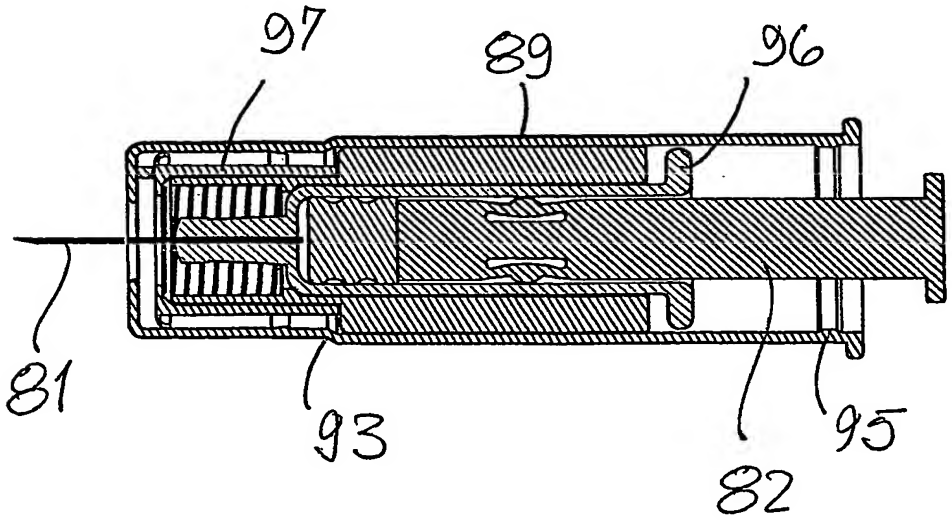


FIG 7F.

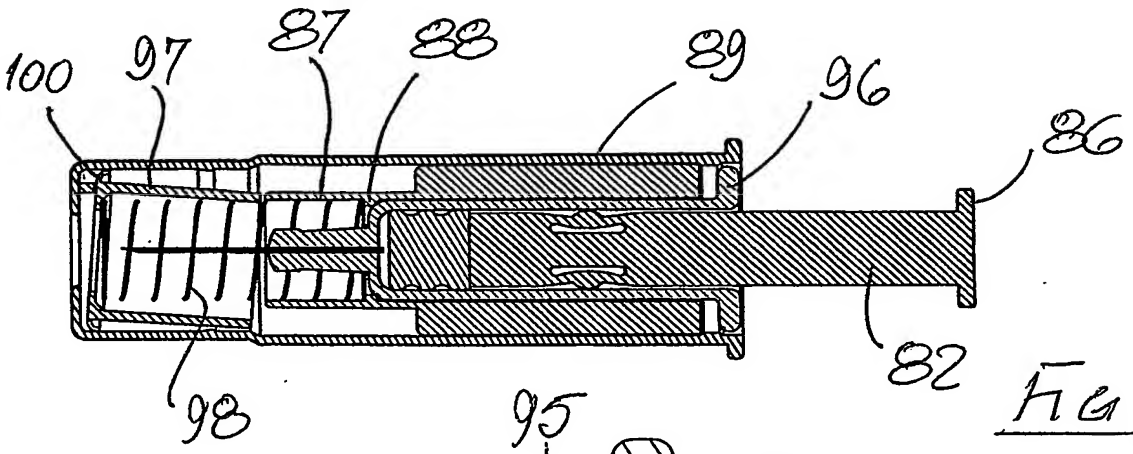


FIG 7G

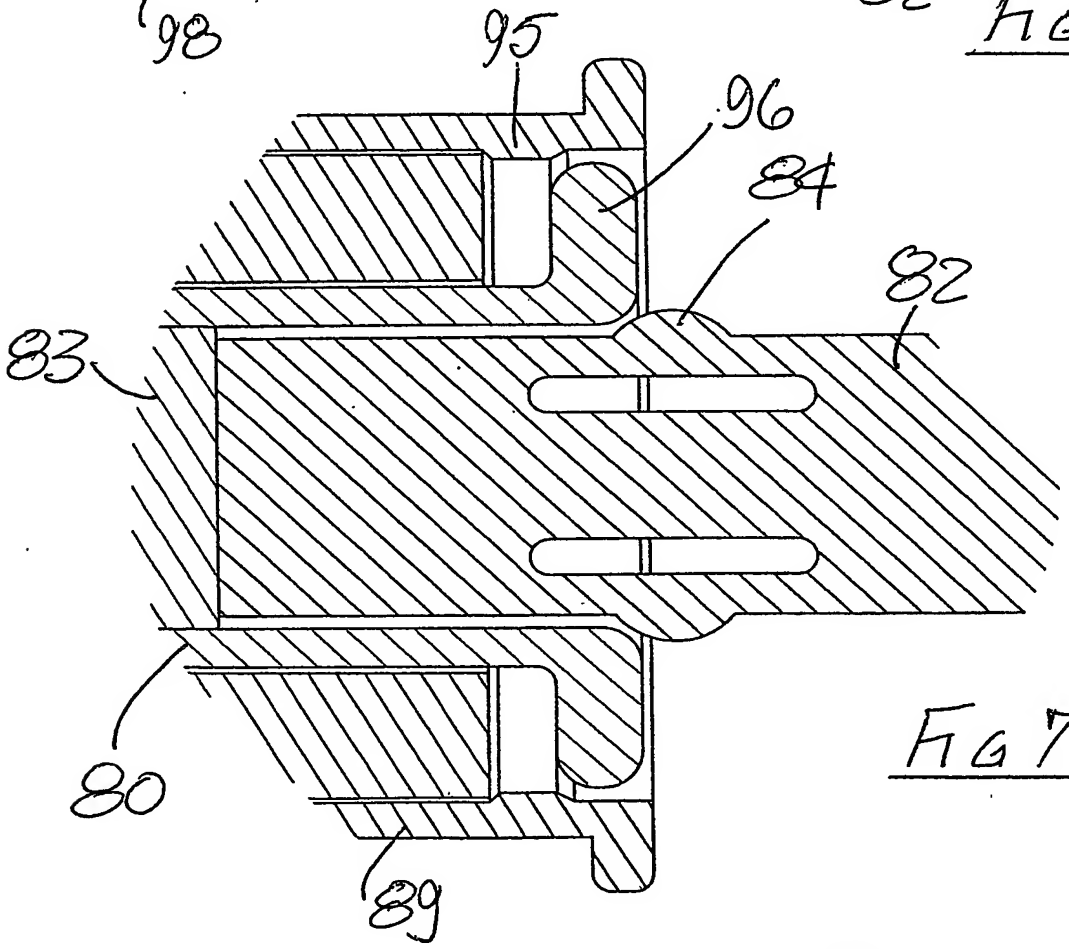


FIG 7H

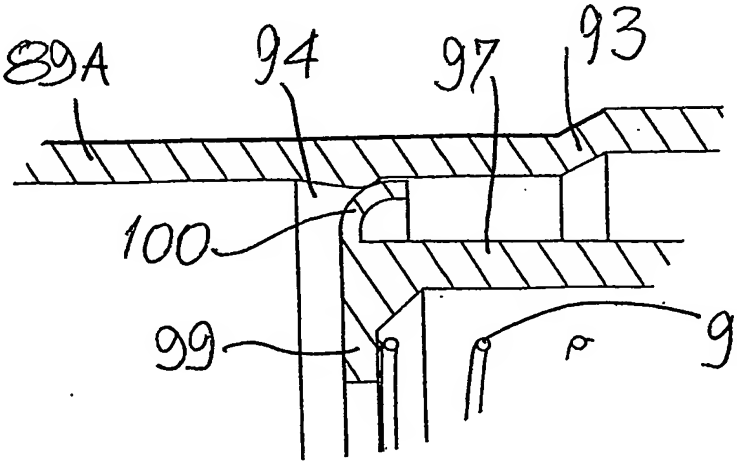


FIG 7J

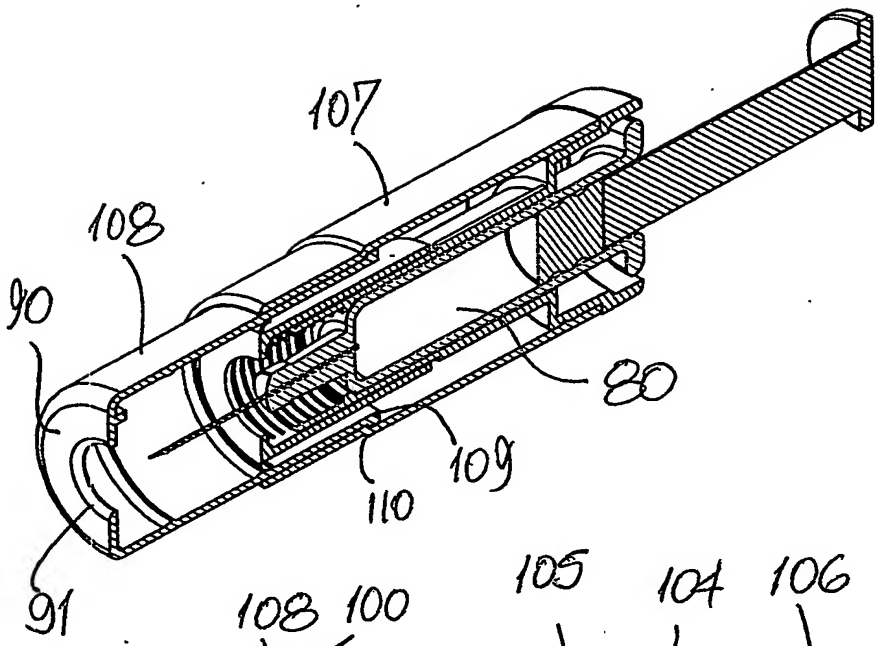


FIG 8A

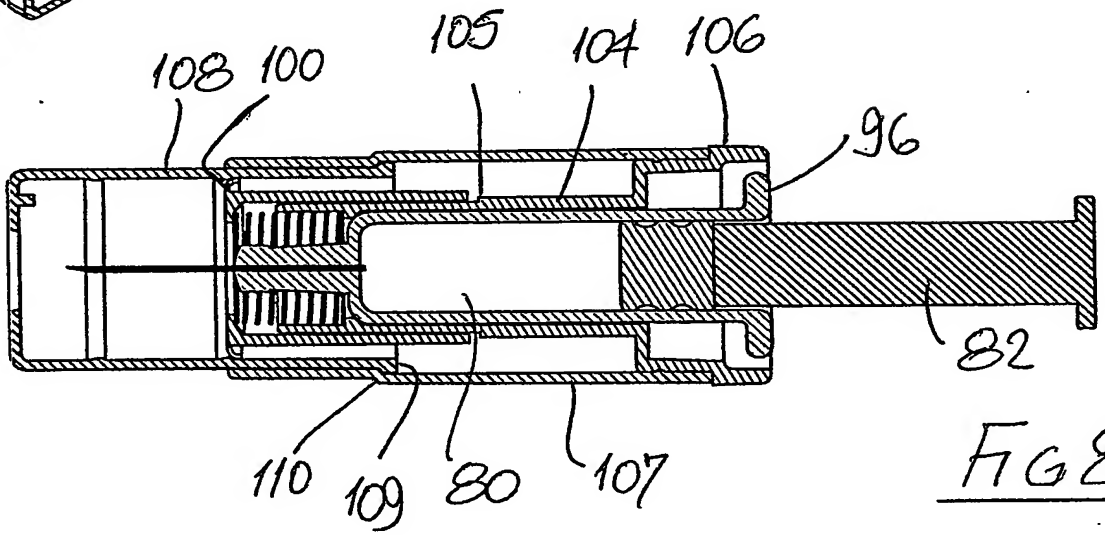


FIG 8B

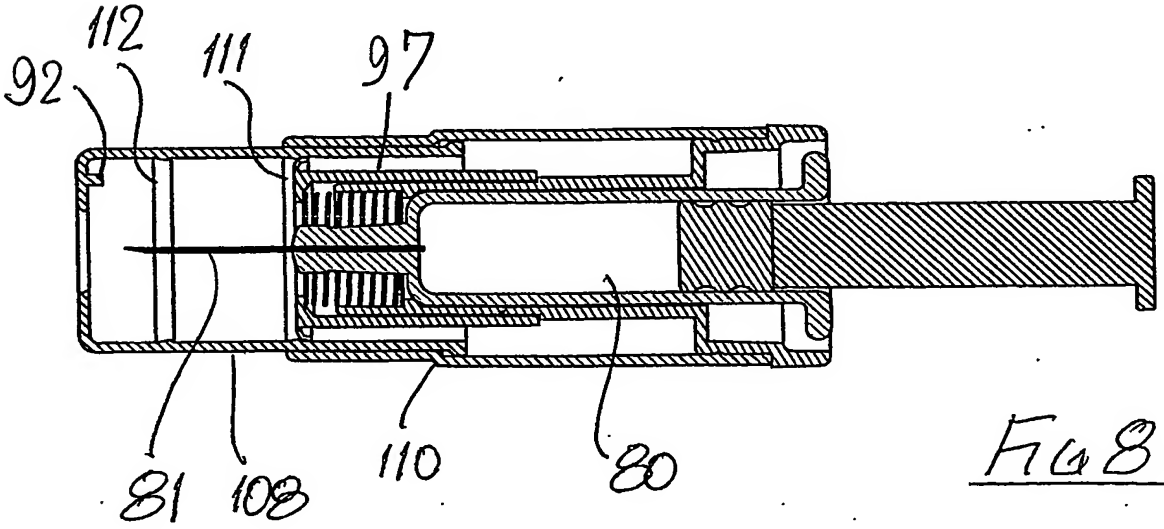


FIG 8C

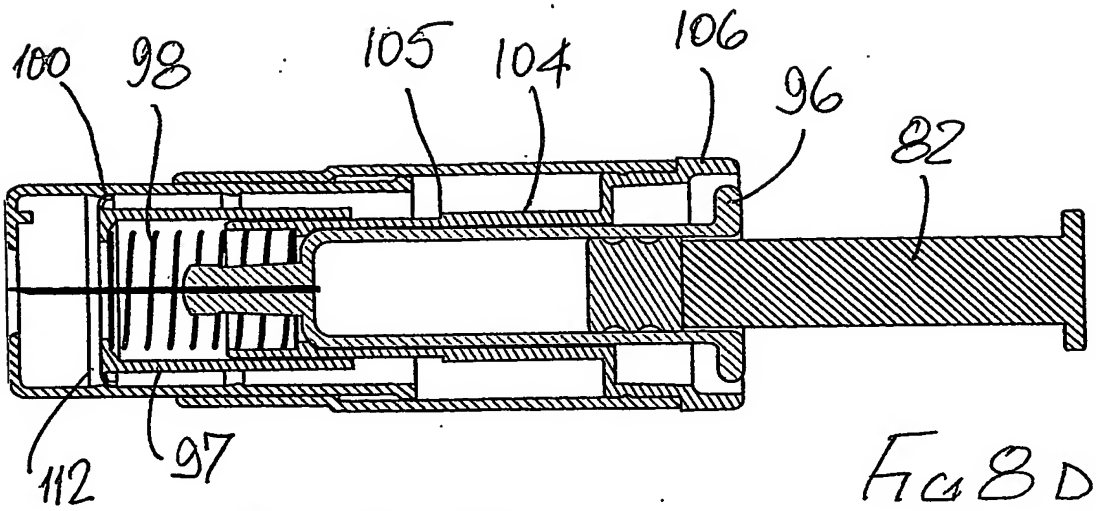


FIG 8D

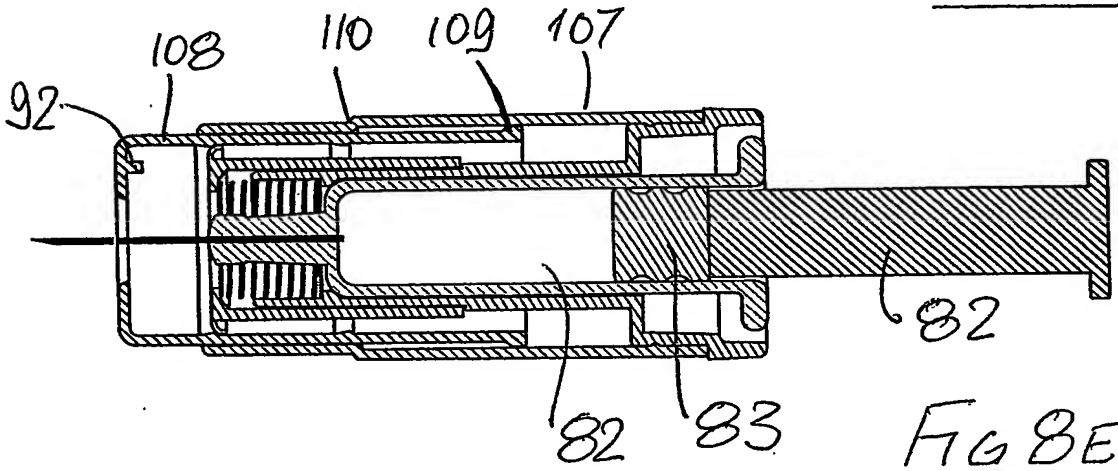


FIG 8E

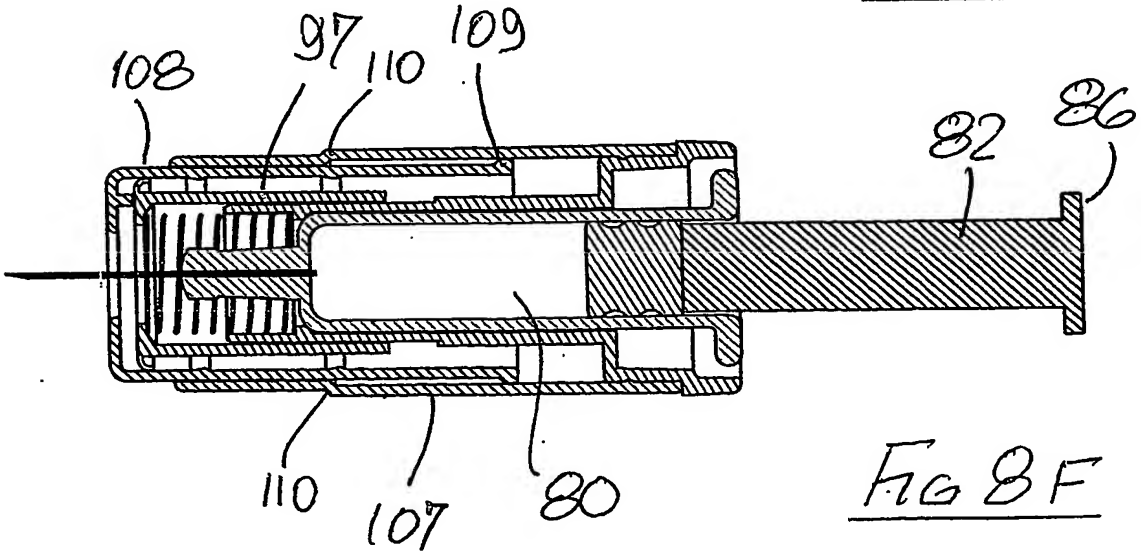


FIG 8F

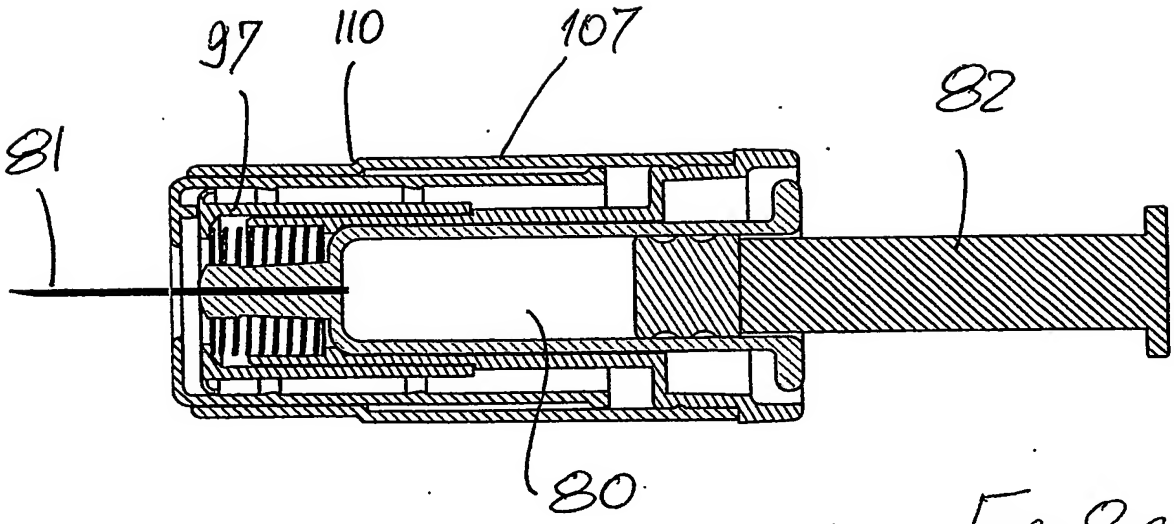


FIG 8G

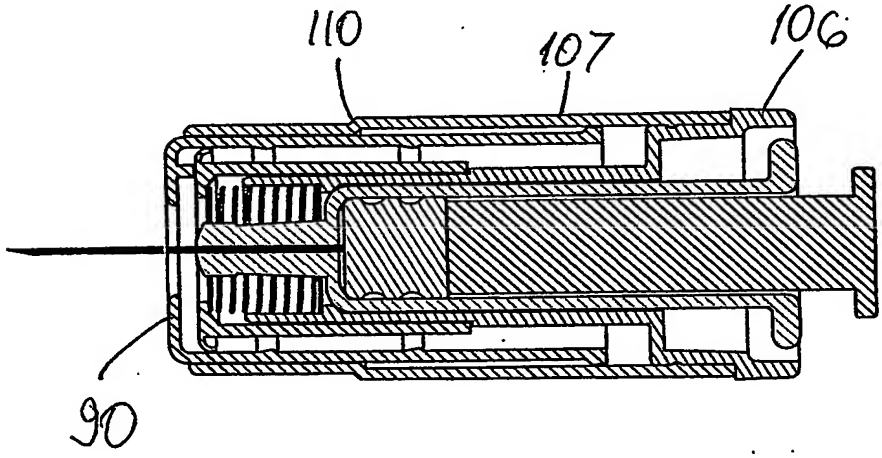


FIG 8H

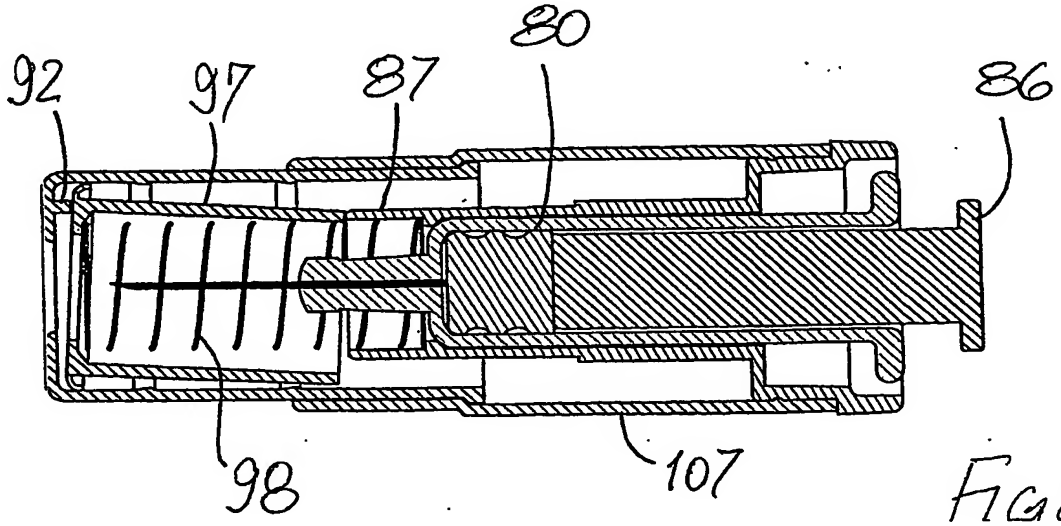


FIG 8J

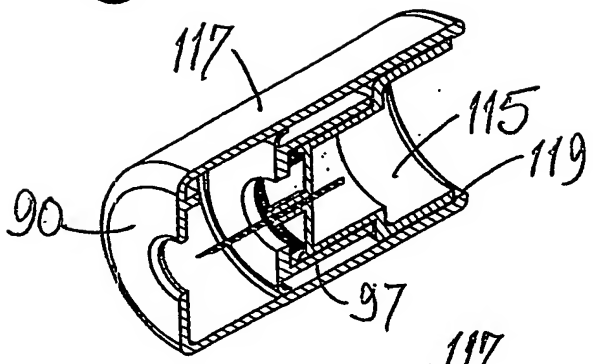


FIG 9A

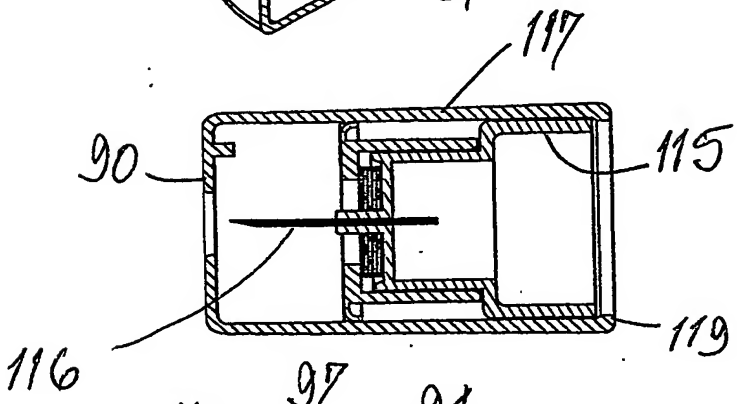


FIG 9B

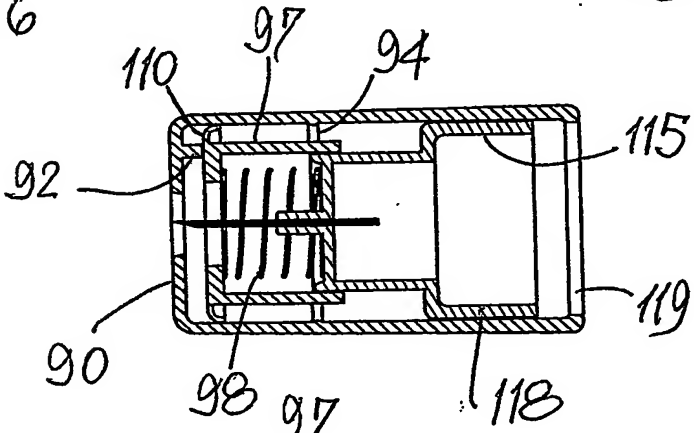


FIG 9C

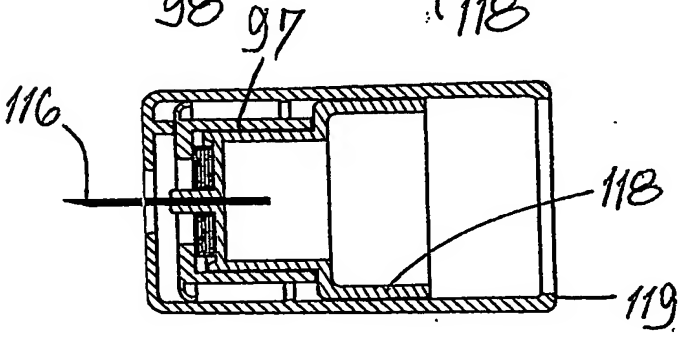


FIG 9D

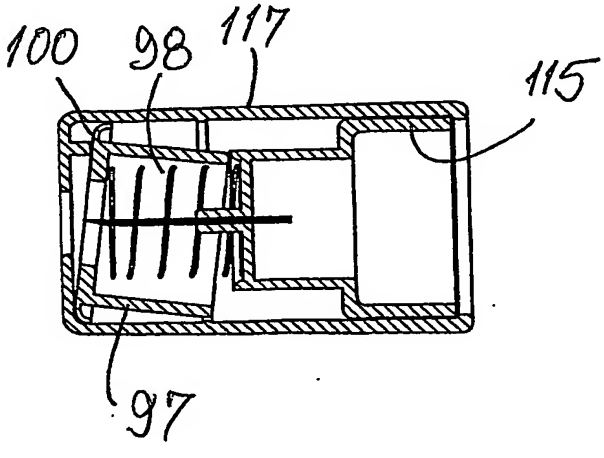


FIG 9E

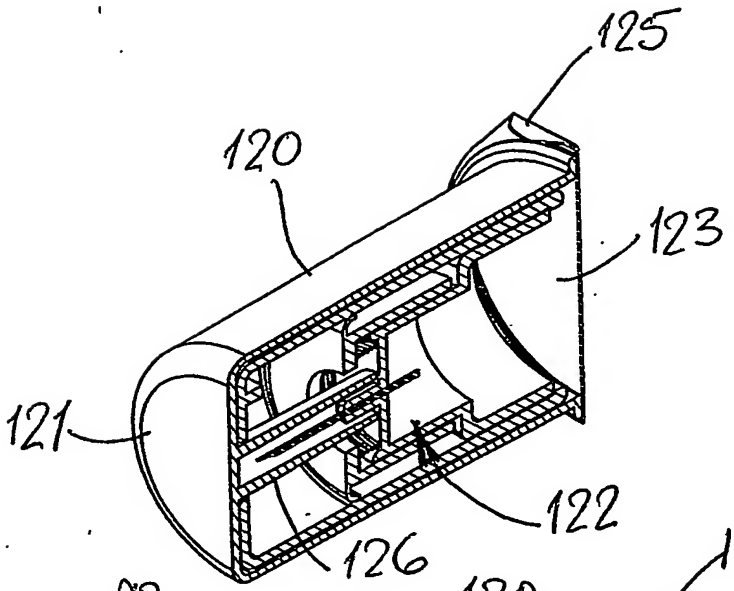


FIG 10A

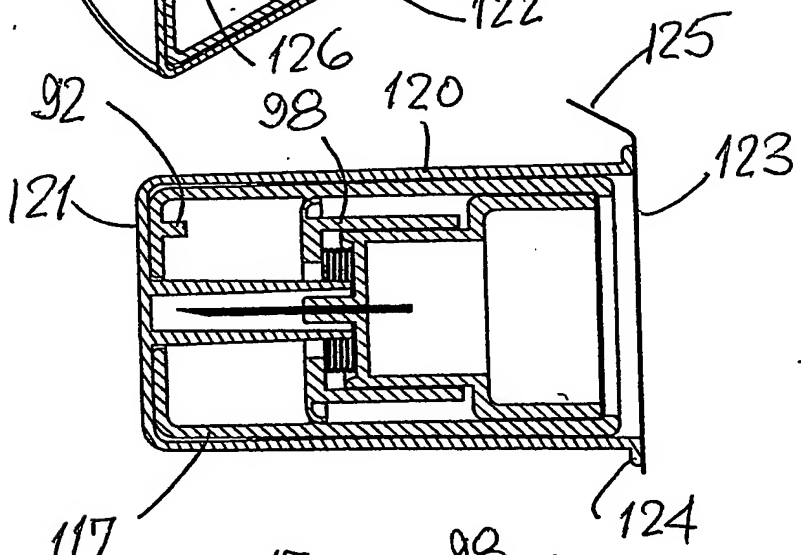


FIG 10B

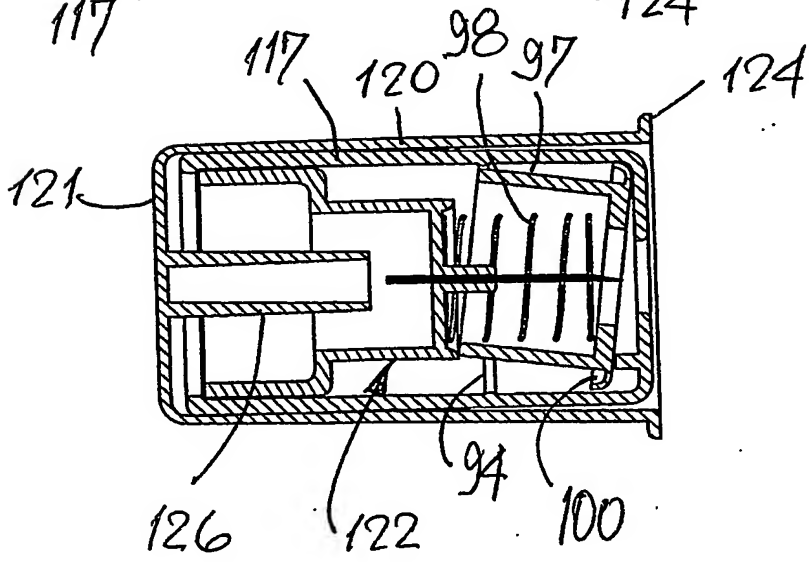


FIG 10C

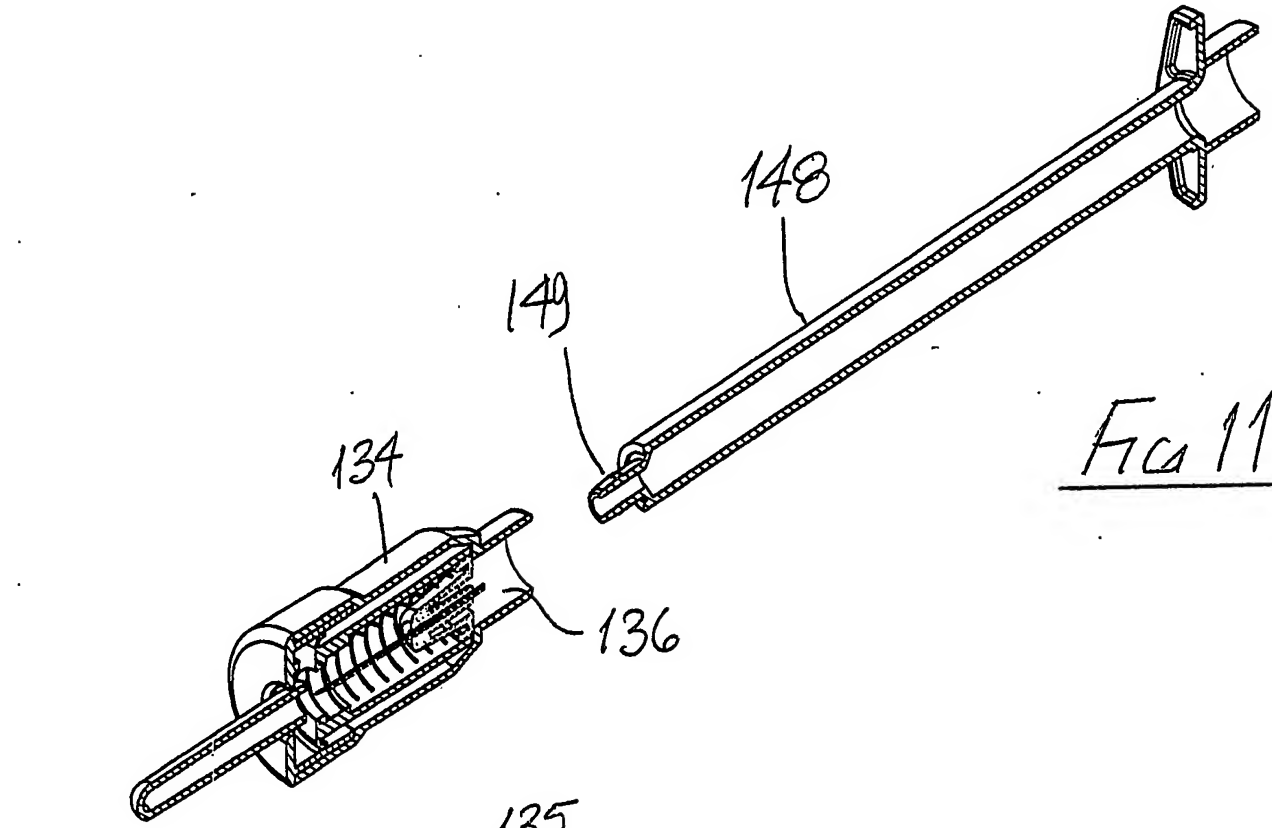


FIG 11A

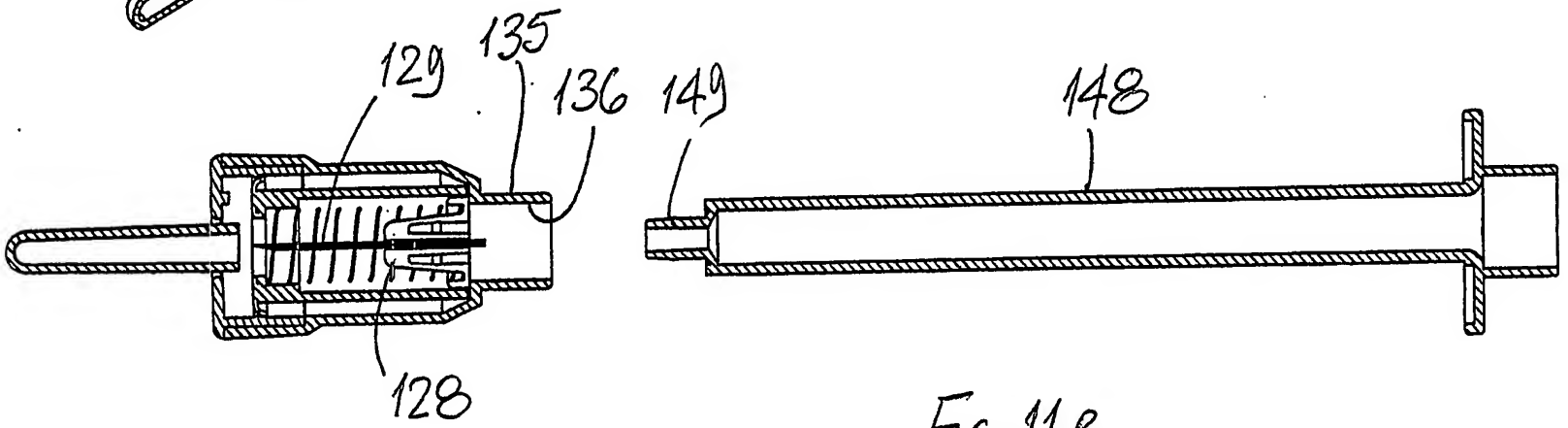


FIG 11B

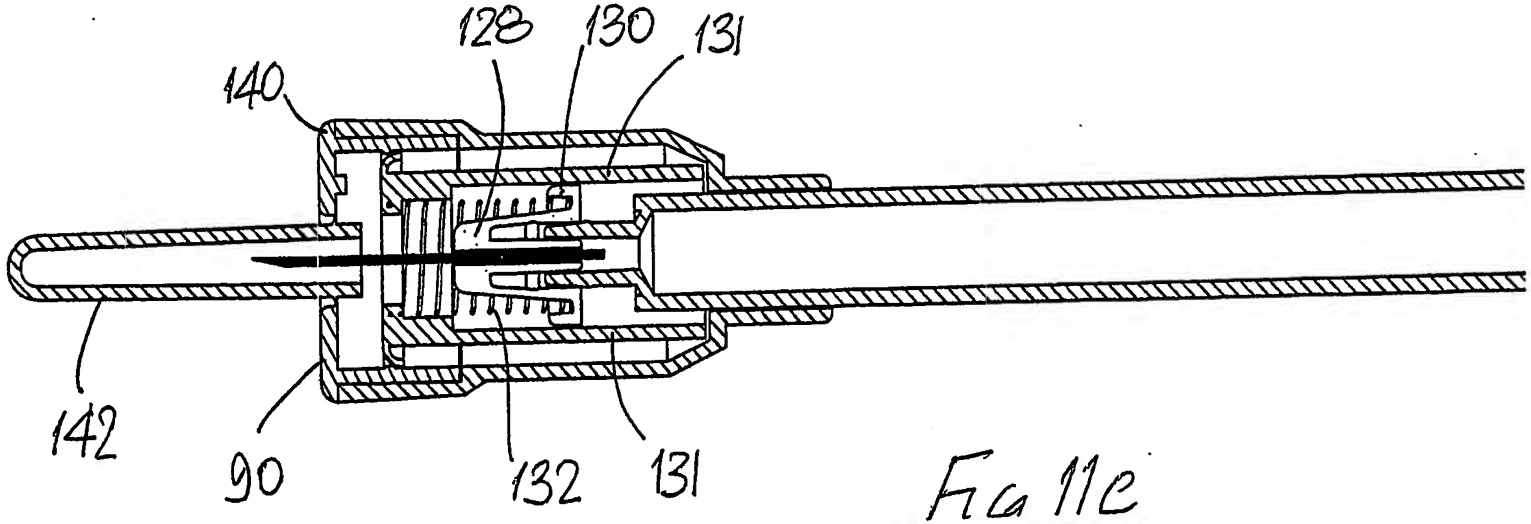


Fig 11C

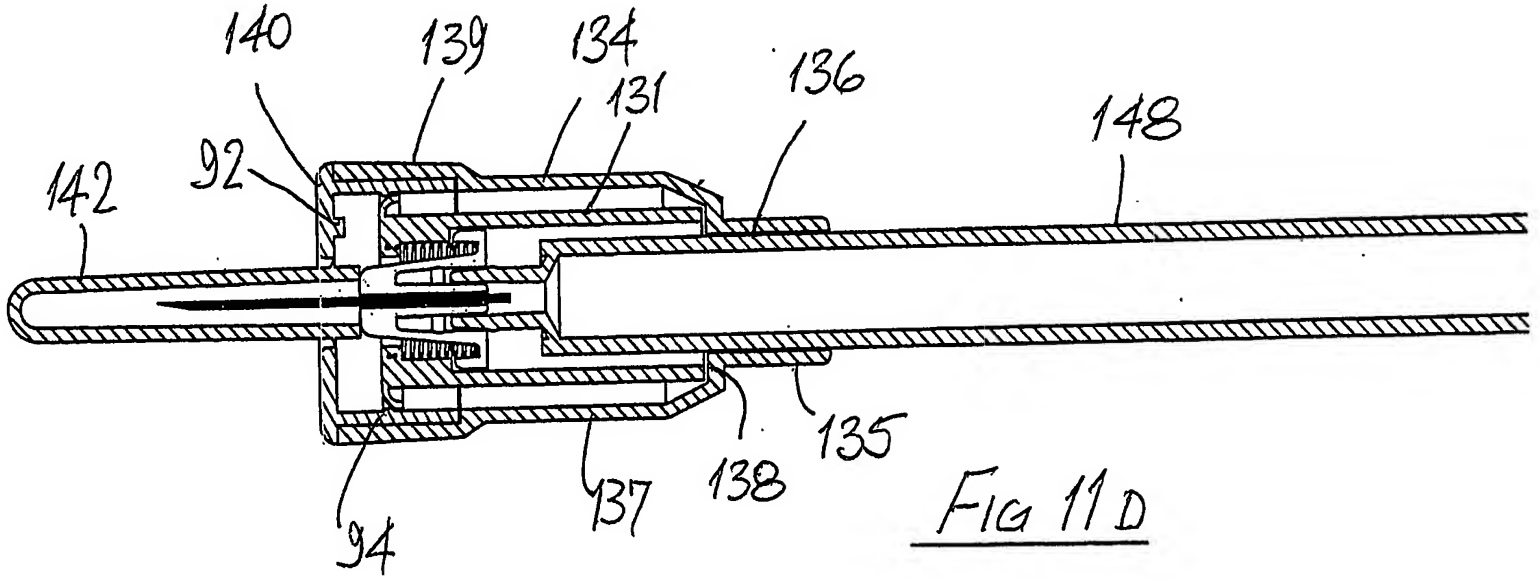


Fig 11D

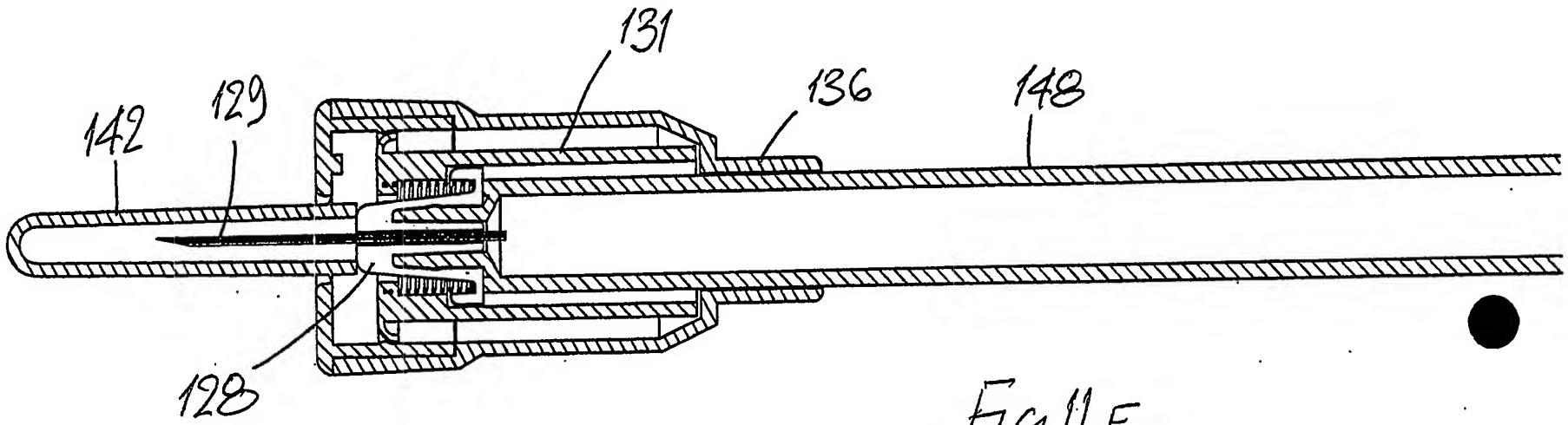


FIG 11E

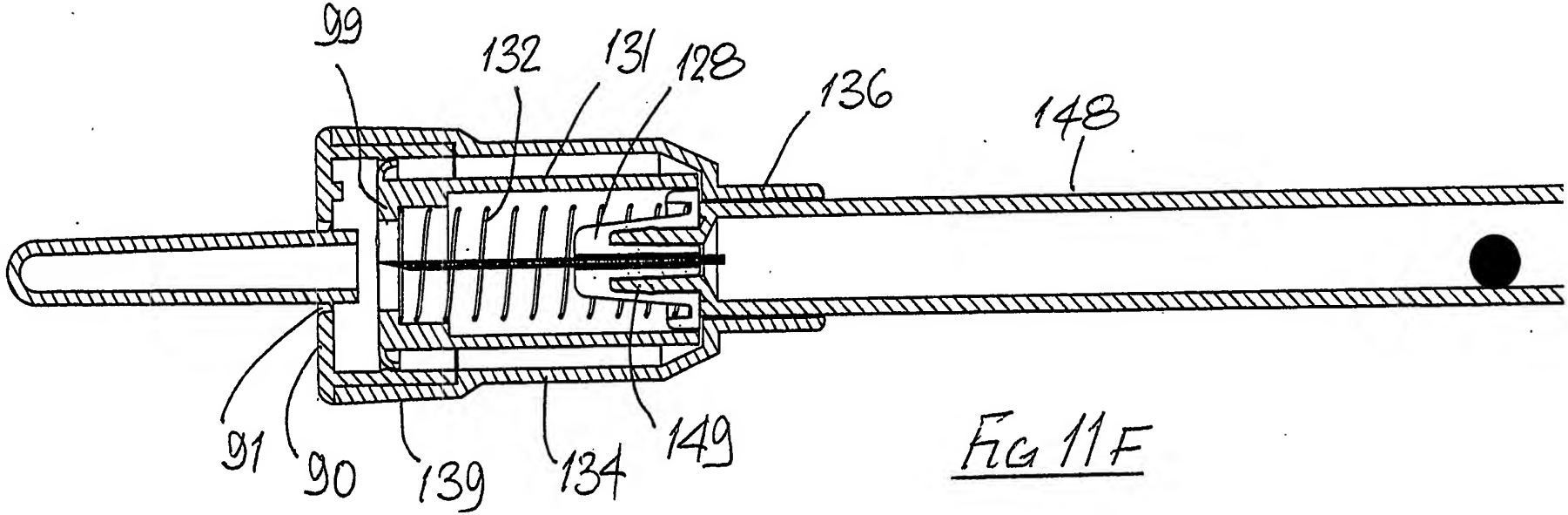


FIG 11F

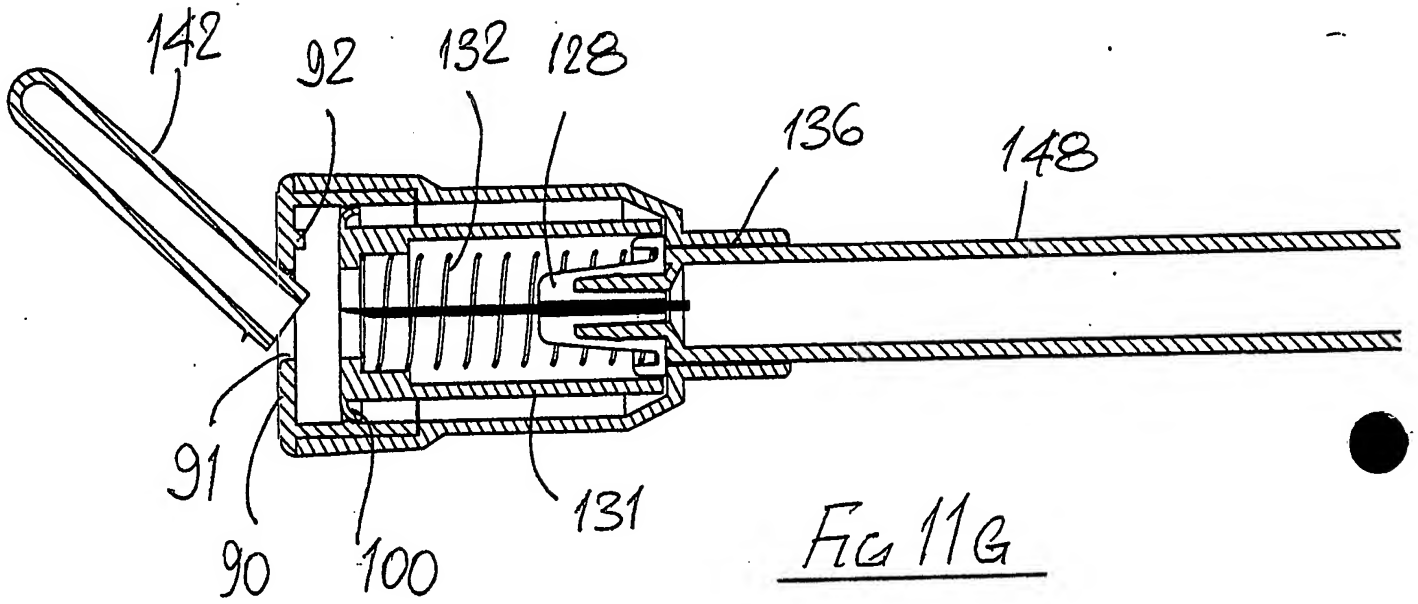


Fig 11G

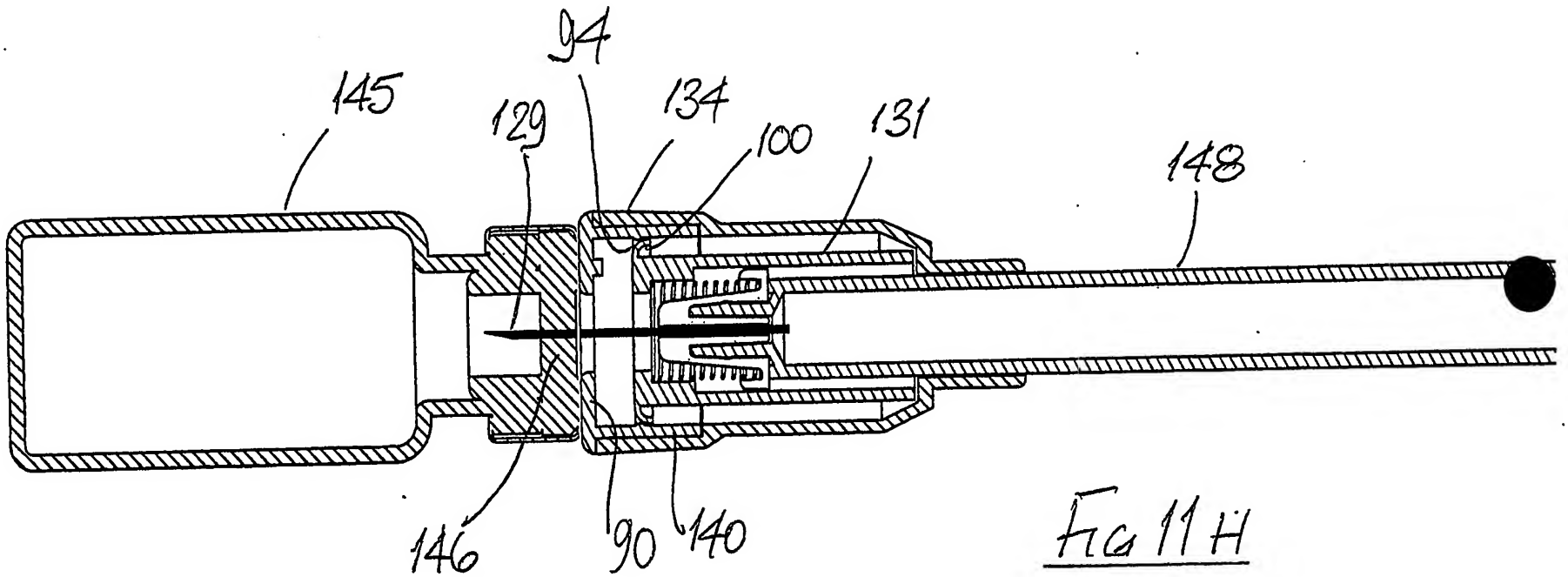


Fig 11H

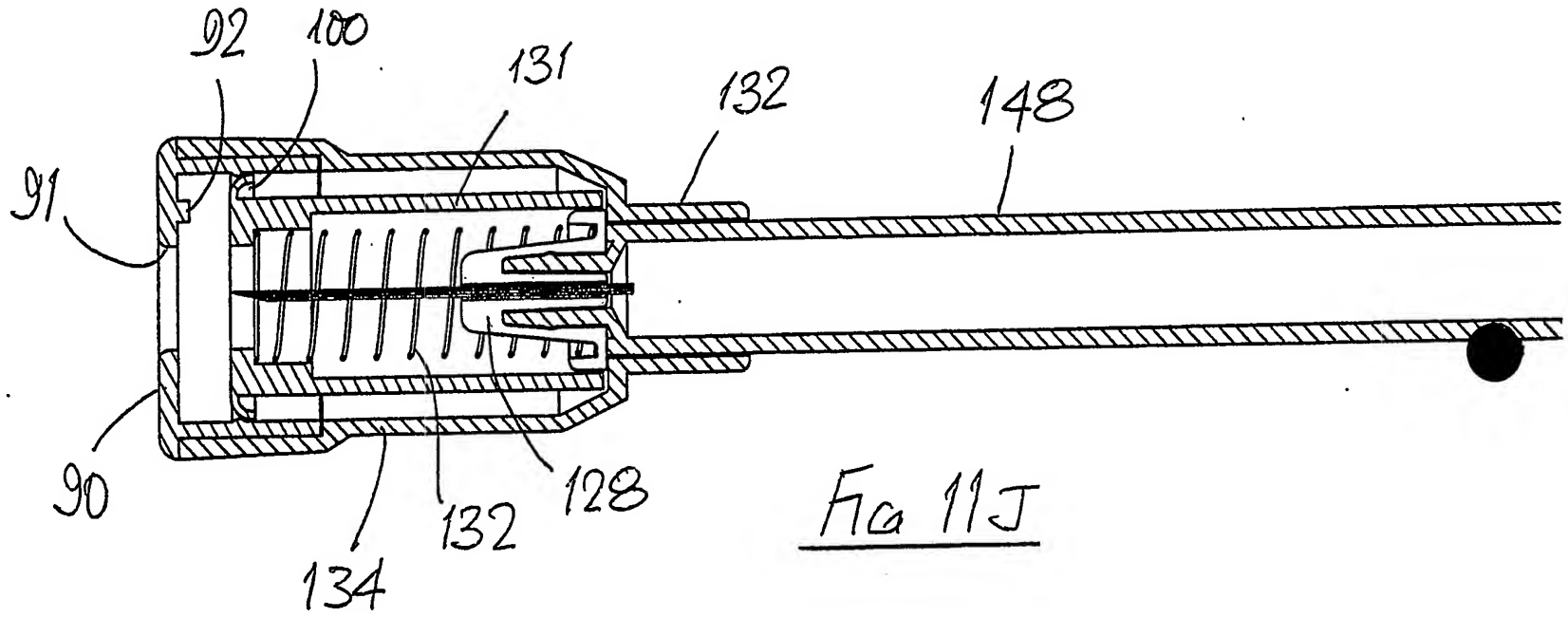


Fig 11J

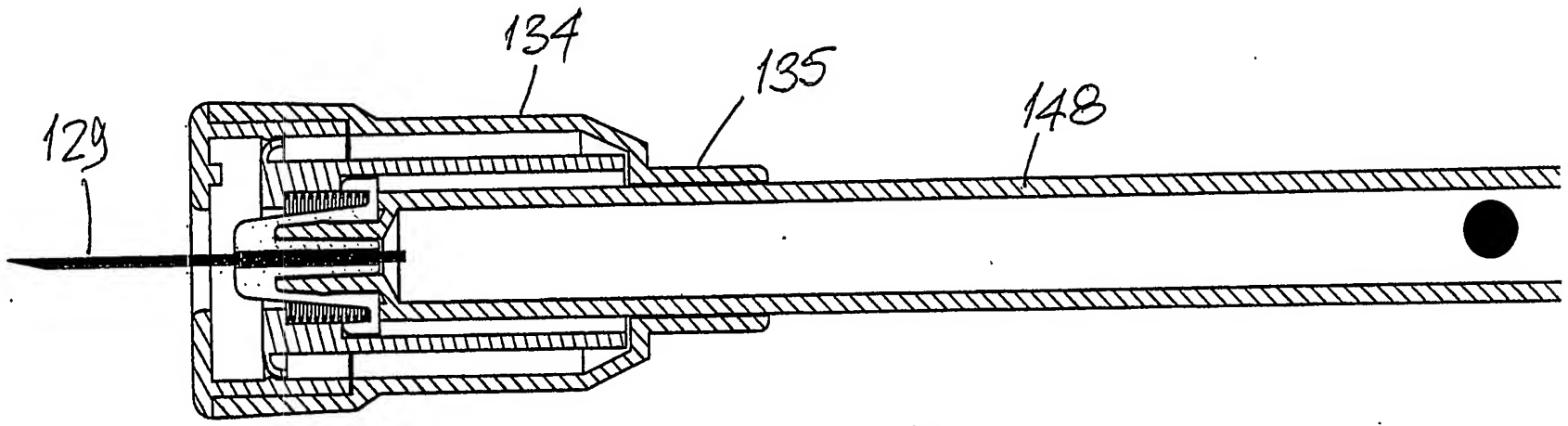


Fig 11K

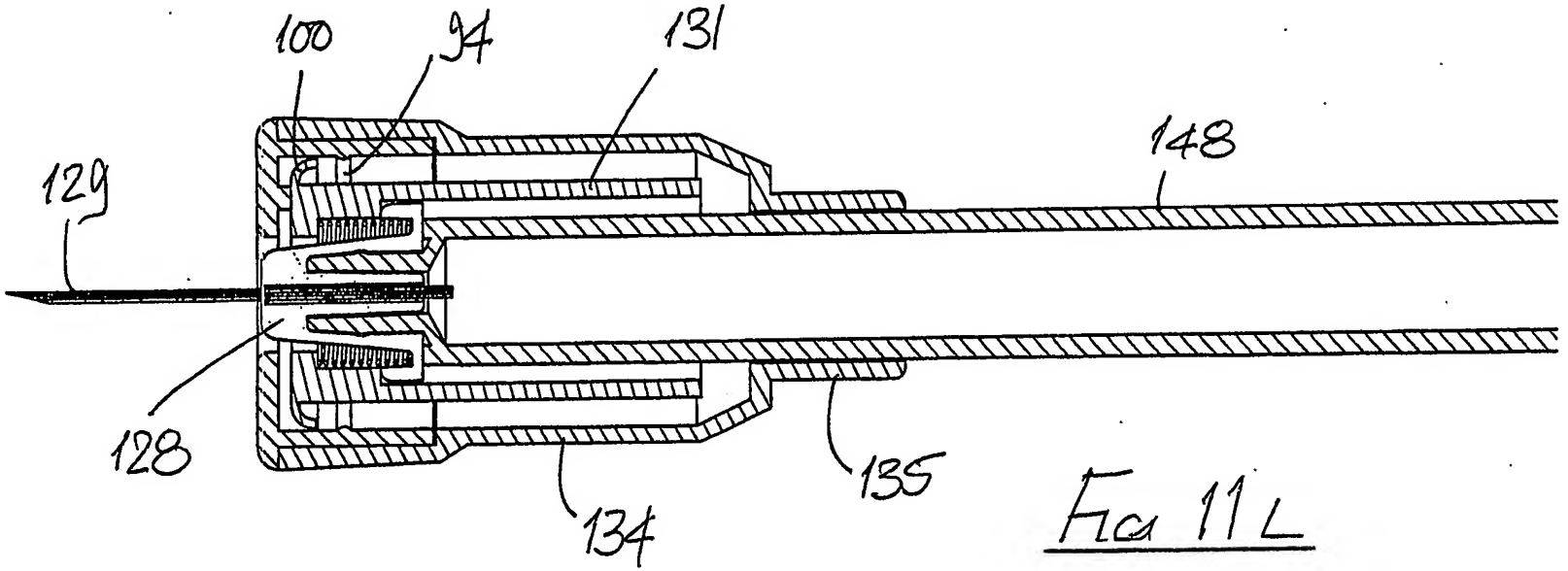


FIG 11L

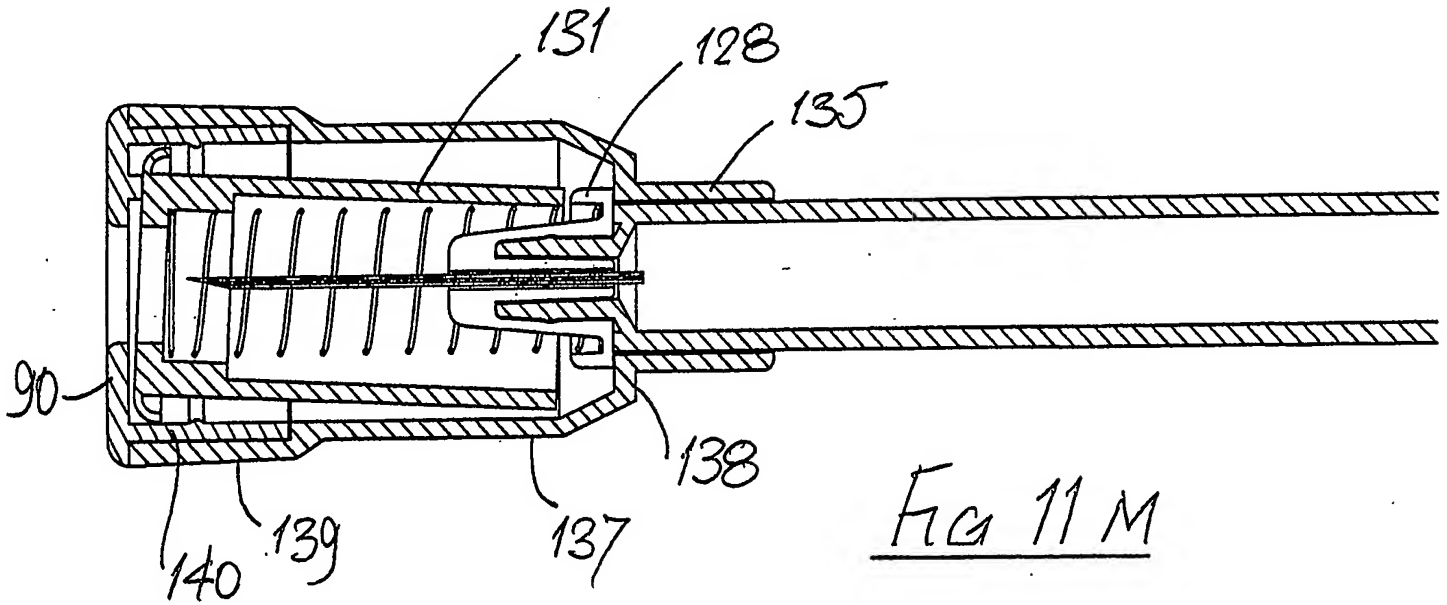


FIG 11M

FIG 12A

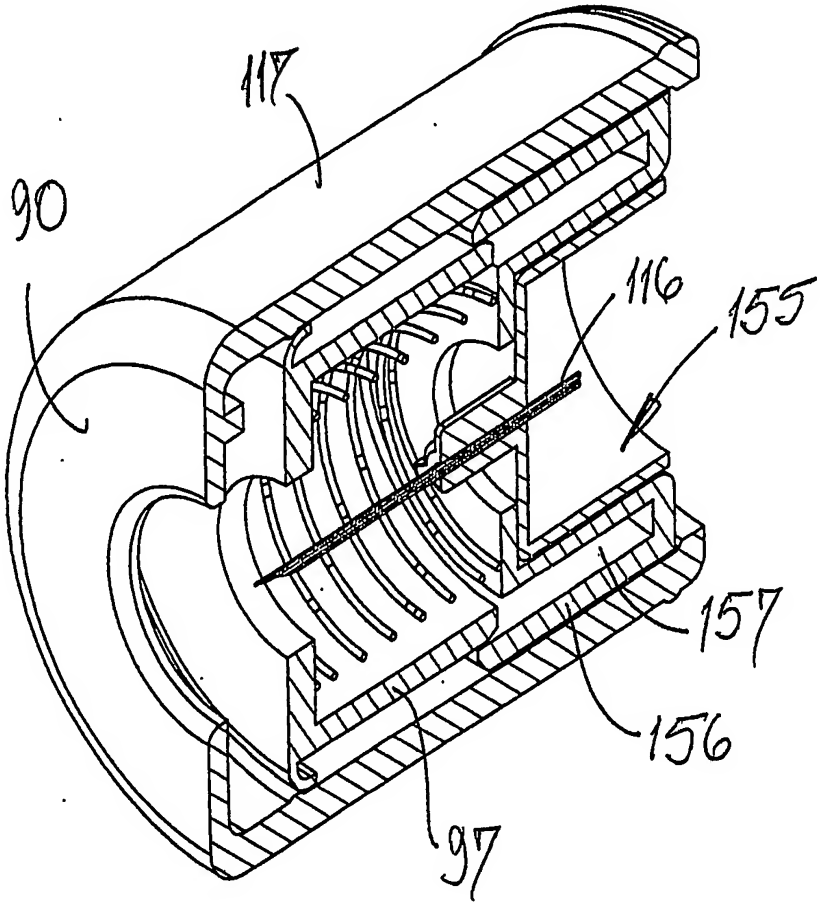
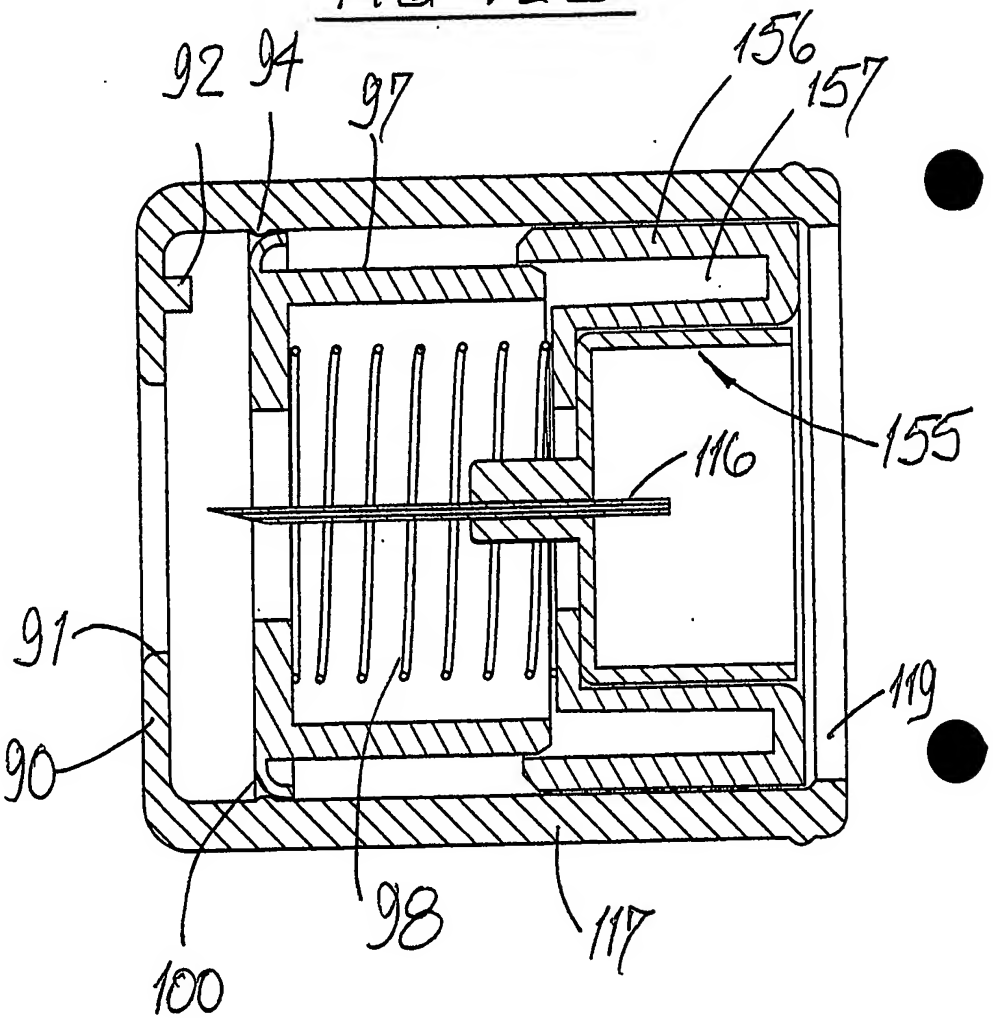


FIG 12B



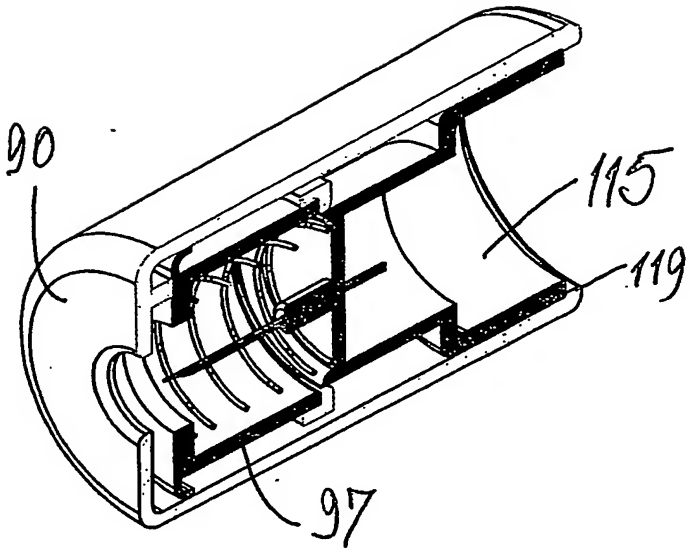


Fig 13A

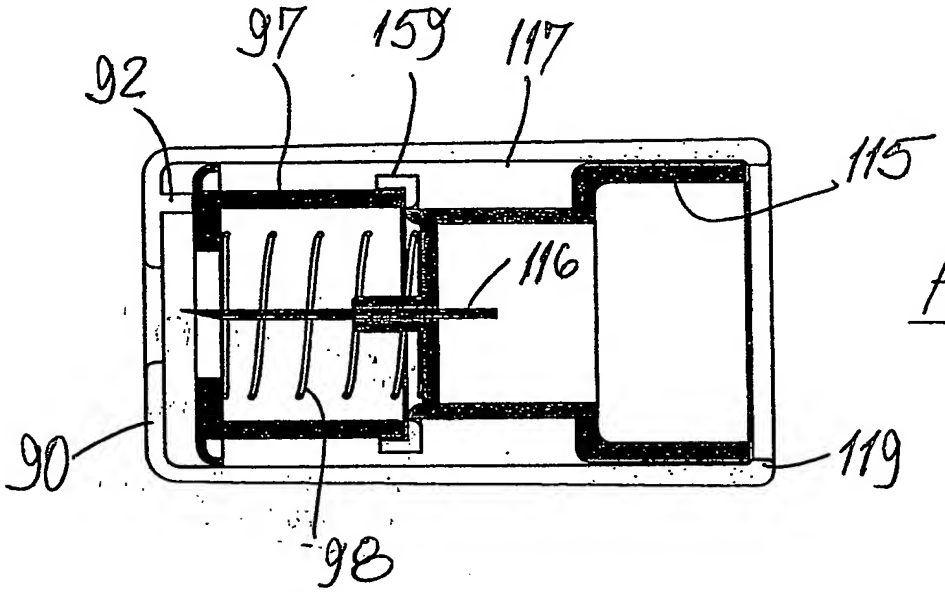


Fig 13B

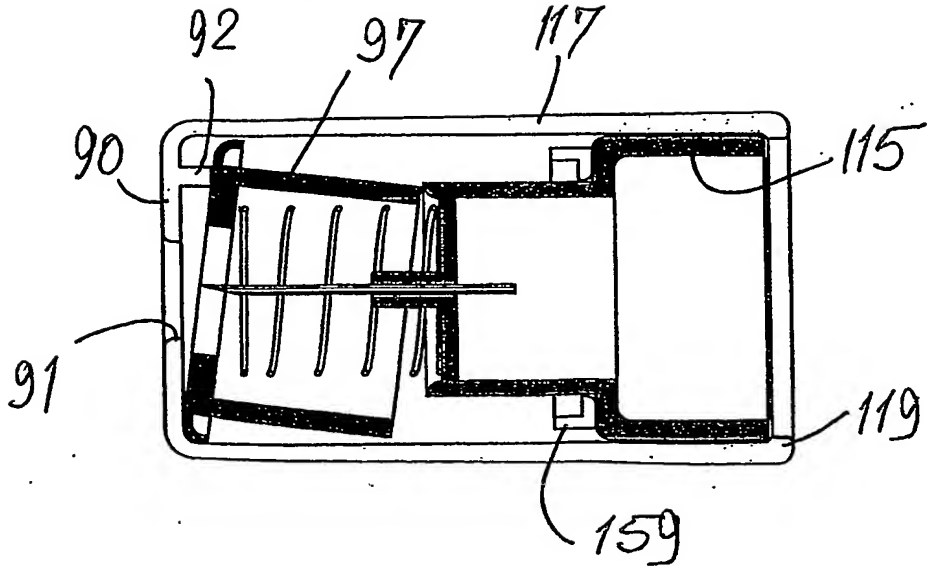


Fig 13C